CellaVision® DM96

USER´S MANUAL 3.0

CELLAVISION

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Preface

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U.S. patents no. 6268611 and 6341180. Swedish patent no. 517626 and 520829. Other patents pending.

Caution

US federal law restricts this device to sale by or on the order of a physician (or properly licensed medical practitioner).

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1 Introduction

1.1 About this User's Manual

This User's manual will guide you step-by-step through the activity sequence of normal use of CellaVision® DM96 (also referred to as the system), aiming for an efficient way to give you good understanding and knowledge of the system and its features. References are made to appendices providing additional information. Some self-explaining dialogs have been left out in the text.

Typographical conventions:

- Names of keys and on-screen objects with which you interact are presented in italics: e.g. click *PRINT*.

Note! *This User's manual covers all applications (e.g. Peripheral Blood and Body Fluid applications) available for the CellaVision DM96 system. The applicability of some sections in this User's manual may therefore depend on the applications installed on the system. Contact your local distributor for more information.*

1.1.1 Warnings and Precautions

Study the meaning of symbols and safety alerts carefully and always use the system in the safest possible manner. Read all instructions carefully before starting to use the system. Using it without being suitably qualified, or in a manner not specified in this User's manual, may damage or deteriorate the system, cause misleading results or even lead to injury.

Warning alerts appear in this manual as follows:

Alert	Explanation
WARNING	May cause injury.
Caution	May cause damage to the system.
Important	May cause misleading results.

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Place the system on a steady table. Do not place it where it is exposed to bumps or vibrations, excessive temperature variations or direct sunlight. The system must be connected to grounded electrical sockets only. Authorized personnel should do the initial installation and reinstallation after moving the system. Do not install or run any software not supplied with the system. To maintain electromagnetic compatibility, use only original components. Spillage of fluid on the surfaces of the system may cause malfunctions or deterioration. Wipe off spilled fluids immediately with a soft tissue.

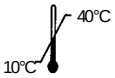
WARNING

The system should be serviced by authorized personnel only.

WARNING

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

The following symbols are found on the system:

Symbol	Explanation
	Indicates that the surface becomes hot and should not be touched with bare hands.
	Documentation needs to be consulted.
	In vitro diagnostic medical device
	Temperature limitation
	This symbol is only valid in the European Community and indicates separate disposal of waste of electrical and electronic equipment
	On (Supply).
	Off (Supply).

1.2 Intended Use of CellaVision DM96

CellaVision® DM96 is an automated system intended for in-vitro diagnostic use.

CellaVision DM96:

- Scans a user-defined part of a microscope slide;
- Automatically locates and presents images of cells on smears from various specimens;
- Is intended to be used by skilled operators.

1.2.1 Peripheral Blood Application

The peripheral blood application (PB) is intended for differential count of white blood cells, characterization of red blood cell morphology and platelet estimation. The system automatically locates and presents images of blood cells on peripheral blood smears. The operator identifies and verifies the suggested classification of each cell according to type.

1.2.2 Body Fluid Application

The body fluid application (BF) is intended for differential count of white blood cells. The system automatically locates and presents images of cells on cytocentrifuged body fluid preparations. The operator identifies and verifies the suggested classification of each cell according to type.

1.3 General Description of CellaVision DM96

CellaVision DM96 consists of a slide feeder unit, an optic unit consisting of a microscope and camera (referred to as a slide scanning unit) and a computer system containing the acquisition and classification software CellaVision® DM software. It is important that slide preparation is performed according to standardized methods (see Appendix G — Slide Preparation Guidelines).

General Functionality of the System:

- Receives order information from and sends results to the LIS;
- Locates and presents images of every located cell or object found on the smear;
- Stores images and results in a database;
- Presents an overview image of a user-defined area on a slide.

1.3.1 Peripheral Blood Application

General Functionality

- Presents an image on a screen of every located cell or object;
- Organizes and suggests cell classification (preclassification) for white blood cells;
- Makes it possible to identify, confirm or modify (reclassification) the suggested classification of white blood cells;
- Presents and suggests morphological characteristics (precharacterization) in an overview image of red blood cells;
- Makes it possible to confirm or modify the precharacterization of red blood cell morphology;
- Presents an overview image and facilitates platelet estimation.

WBC Preclassification

The system preclassifies the following WBC classes: *Band neutrophils, Segmented neutrophils, Eosinophils, Basophils, Lymphocytes, Monocytes, Promyelocytes, Myelocytes, Metamyelocytes, Blast cells, Lymphocytes variant forms* and *Plasma cells*.

The system preclassifies the following non-WBCs: *Erythroblasts (NRBC), Giant thrombocytes, Thrombocyte aggregations, Smudge cells* and *Artefacts*. Non-WBCs are reported as number of cells or objects /100 WBC.

Unidentified is a class for cells and objects which the system has preclassified with a low confidence level.

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WBC Reclassification for Peripheral Blood

Besides the cell classes mentioned above, the operator can reclassify cells into the following classes: *Immature eosinophils, Immature basophils, Promonocytes, Prolymphocytes, Large granular lymphocytes, Hairy cells, Sézary cells, Other, Megakaryocytes, Not classed* and 15 user defined cell classes.

Other should be used for cells which the operator identifies as a WBC, but of a type other than those listed. WBCs put here will be included in the differential count.

Not classed should be used for cells and objects which the operator cannot identify and wants to exclude from the differential count.

RBC Precharacterization

The system precharacterizes the following RBC morphology characteristics in an overview image: *Polychromasia, Hypochromasia, Anisocytosis, Microcytosis, Macrocytosis and Poikilocytosis.*

RBC characterization

The operator can characterize to *Target cells, Schistocytosis, Helmet cells, Sickle cells, Spherocytosis, Elliptocytosis, Ovalocytosis, Tear drop cells, Stomatocytosis, Acanthocytosis, Echinocytosis, Howell-Jolly bodies, Pappenheimer bodies, Basophilic stippling, Parasites* and 10 user defined characteristics.

Platelet Estimation

The operator counts or estimates platelets in an overview image.

Sample Preparation

To perform a peripheral blood differential count a thin blood film is wedged on a glass slide (a blood smear) from a peripheral blood sample and stained with Romanowsky stain (see Appendix G — Slide Preparation Guidelines for recommended staining recipes).

1.3.2 Body Fluid Application

General Functionality

- Presents an image on a screen of every located cell or object;
- Organizes and suggests cell classification (preclassification) for the located blood cells;
- Makes it possible to identify, confirm or modify (reclassification) the suggested classification of the located cells;
- Presents an overview image.

Preclassification for Body Fluid

The system preclassifies the following WBC classes: *Neutrophils*, *Eosinophils*, *Lymphocytes*, *Macrophages (including Monocytes)* and *Other*. Cells pre-classified as *Basophils*, *Lymphoma cells*, *Atypical lymphocytes*, *Blasts* and *Tumor cells* are automatically forwarded to the cell class *Other.*

Unidentified is a class for cells and objects which the system has pre-classified with a low confidence level.

The system preclassifies the following non-WBCs: *Smudge cells* and *Artefacts*. Non-WBCs are reported as number of cells or objects /100 WBC.

WBC Reclassification for Body Fluid

Besides the cell classes mentioned above, the operator can reclassify cells into the following cell classes: *Not classed* and user defined cell classes.

Not classed should be used for cells and objects which the operator cannot identify and wants to exclude from the differential count.

Sample Preparation

Body fluid samples are prepared by using a cytocentrifuge and a staining unit. The sample is centrifuged onto a glass slide and stained with Romanovsky stain (see Appendix G — Slide Preparation Guidelines for recommended staining recipes).

Limitations

A significant number of samples have not been evaluated for the following fluid types: pericardial, abdominal, drain, CAPD and bronchoalveolar lavage. Therefore, they are not included in the statistical analysis.

1.3.3 CellaVision® Remote Review

CellaVision Remote Review is an additional software to CellaVision® DM96. The software gives remote users access to analyzed slides and the possibility to reclassify cells and sign slides from another location. A slide being verified on CellaVision DM96 can simultaneously be opened on a CellaVision Remote Review and vice versa. CellaVision® Remote Review is intended to be used with the Peripheral Blood and the Body Fluid applications. See 9 CellaVision® Remote Review — Multiple Users for more information.

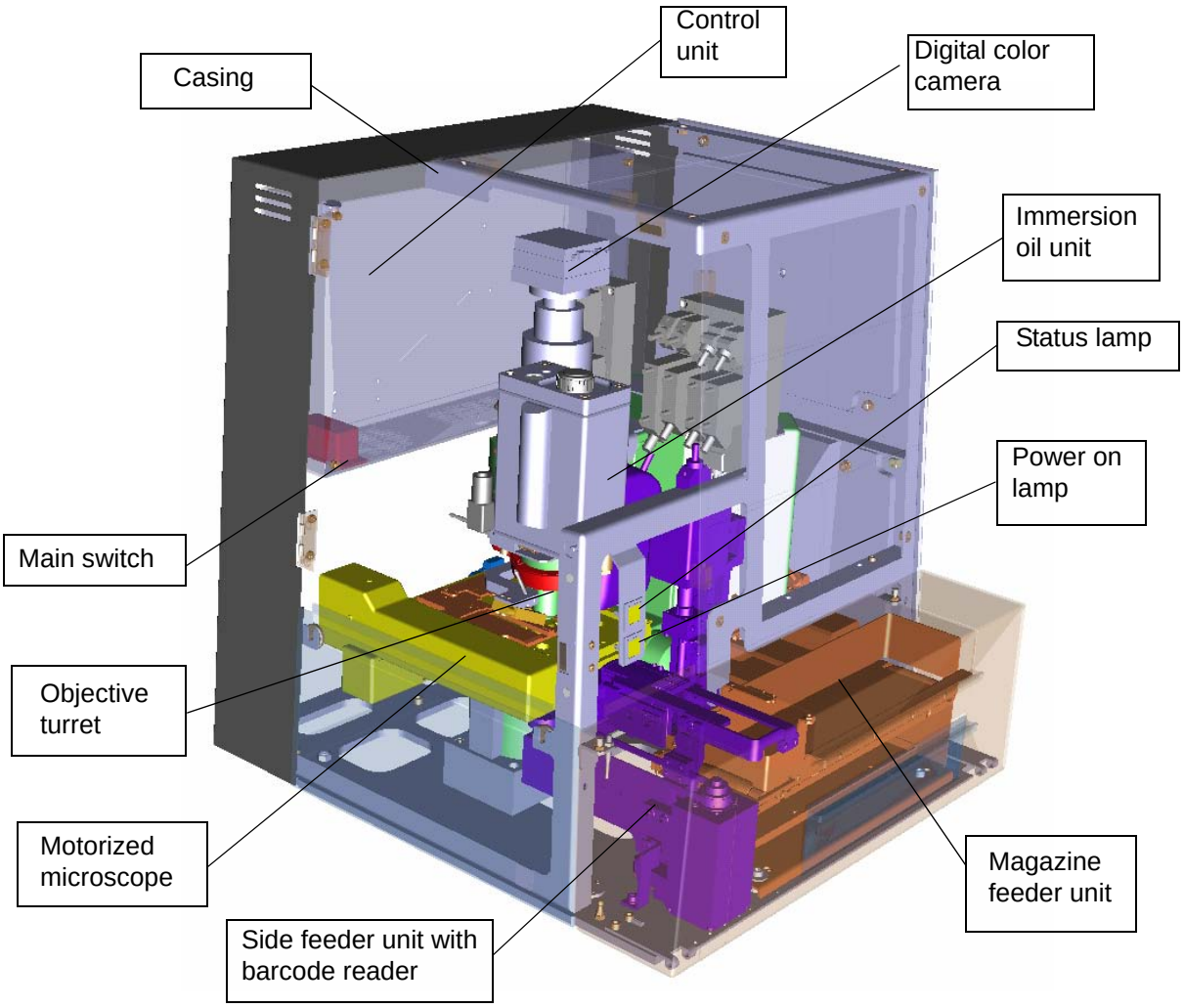
1.4 Components and Mechanical Operation

1.4.1 Major Parts of the System

The system comprises the following major units:

- Computer system
- Slide scanning unit (SSU)
  - Motorized microscope
  - Digital color camera
  - Immersion oil unit
  - Slide feeder unit with barcode reader
  - Magazine feeder unit
  - Control unit
  - Casing

Slide Scanning Unit:



WARNING

Keep your fingers clear from the objective turret, otherwise personal injury may result.

WARNING

Do not remove the rear cover, dangerous voltages inside.

WARNING

The oil may cause sensitization by skin contact. We recommend using gloves.

Motorized Microscope

The motorized microscope is a fixed-XY-stage upright light microscope with a moving objective focus. It has a motorized 5-position objective turret and a 100 W halogen illumination system. The microscope is motorized for fully automated positioning and focusing of the slide during process.

Digital Color Camera

The camera is a high-quality progressive-scan CCD color camera, for maximum image quality and high speed image acquisition.

Immersion Oil Unit

The unit automatically applies drops of immersion oil to a slide. An optical drop counter controls the procedure. The canister capacity is about 500 ml. A sensor detects if the oil level is below 100 ml.

Slide Feeder Unit with Barcode Reader

The slide feeder transports slides from a magazine to the stage and back again after the slide has been processed. It is equipped with a barcode reader which scans the barcode of both the slide and the magazine. For maximum safety, the barcode of the slide is scanned both before and after processing. See Appendix A — System Specification for more information about barcodes.

Magazine

The magazine can be loaded with up to 12 slides (clipped/round corner slides).

Magazine Feeder Unit

The unit moves magazines from the conveyer to the slide feeder unit and from the slide feeder unit to the output drawer. It is equipped with a counter for the number of magazines in the conveyer and a sensor that warns if the output drawer is full.

Control Unit

The control unit controls motors, sensors, oil applying and illumination. It functions as a slave computer to the PC via an unshared 100 Mbit Ethernet connection.

Computer System

A PC system running Microsoft® Windows® XP and CellaVision® DM software.

Casing

The casing comprises a metal cabinet including 5 hatches/drawers: main hatch, lamp hatch, input hatch, service hatch and output drawer.

WARNING

Never tamper with sensors or other safety devices. These make sure that the system can operate without any risk of personal injury.

2 Operating Procedures

2.1 Starting the System

The CellaVision® DM system computer is configured with a Windows policy restricting access to the operating system for the normal user. When starting the PC the user will automatically be logged onto Windows and then the CellaVision DM Software logon window will be displayed.

Start the system as follows:

1. Switch on the slide scanning unit.
2. Switch on the system computer.
   Wait until the status lamp on the slide scanning unit is flashing or continuously lit (see picture in 1.4.1 Major Parts of the System).
3. In the *Log On* dialog, type username, password and select the desired database.
   The following icons indicate available database types:

   Processing database

   Export database

   Scan database

   CellaVision Competency Software database

4. Click *OK*.

2.2 System Control View

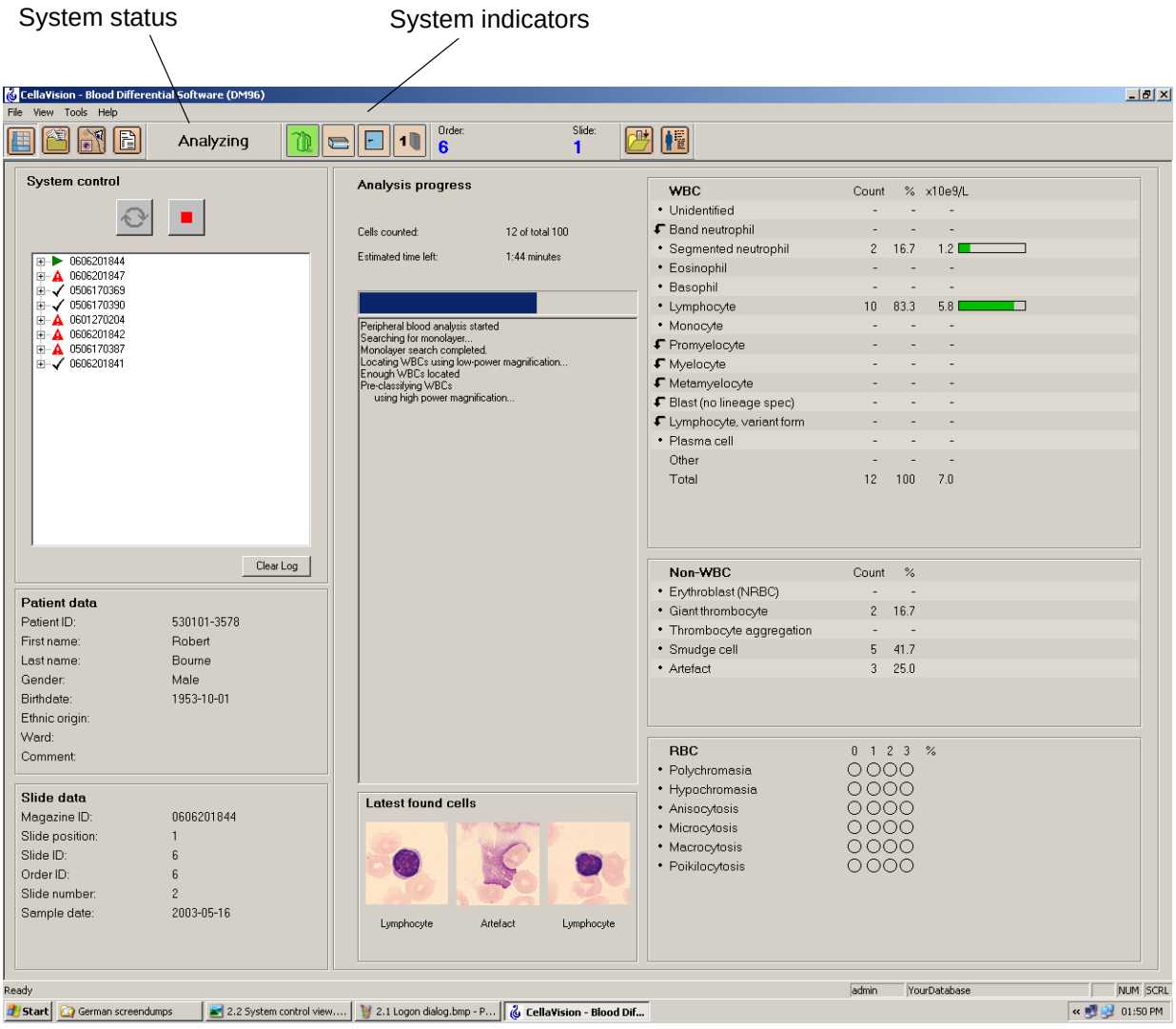
The *System Control View* shows the ongoing slide processing, gives an overview of the preclassification and presents a log of processed slide holders. The layout of the *System Control View* depends on the type of application.

Click *System Control View* in the toolbar.

Information in Toolbar

System indicators show oil level, number of magazines etc. For a description of these indicators, see Appendix C — Buttons and Indicators.

System status is shown as a text: *Idle*, *Analyzing*, *Stopped*, *Paused* or *Error*.



2.3 Slides and Magazines

2.3.1 Barcodes

Important

Only slides labeled with barcodes can be processed. Use only barcode formats appropriate for the system (see Appendix A — System Specification).

Magazine ID

The barcode on the magazine is the magazine ID. When the system has no LIS connection, the magazine ID determines the analysis type.

- Orange magazines with barcodes consisting solely of digits - a peripheral blood analysis will be performed.
- Blue magazines with barcodes consisting of the prefix ‘BFS’ followed by digits - a body fluid analysis will be performed.

Note! *LIS order will override the magazine barcode in determining analysis type.*

Slide ID

The Slide ID is the barcode printed on the slide's label.

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When processing a slide the system searches for order data in the following order:

1. In the database, unsigned orders with the same Order ID.
2. In the database, pending orders.
3. From the LIS.
4. Default values defined in the *Analysis* tab in *Settings*.

2.4 Loading Slides into a Magazine

Load the slide into the magazine with the barcode upwards and towards the operator. 12 slides can be loaded into a magazine. The slide positions in the magazine are numbered 1-12 from the bottom up.

Caution

Use only clipped/round/beveled corner slides. Failing to do so may cause jams and excessive wear on magazines and the system.

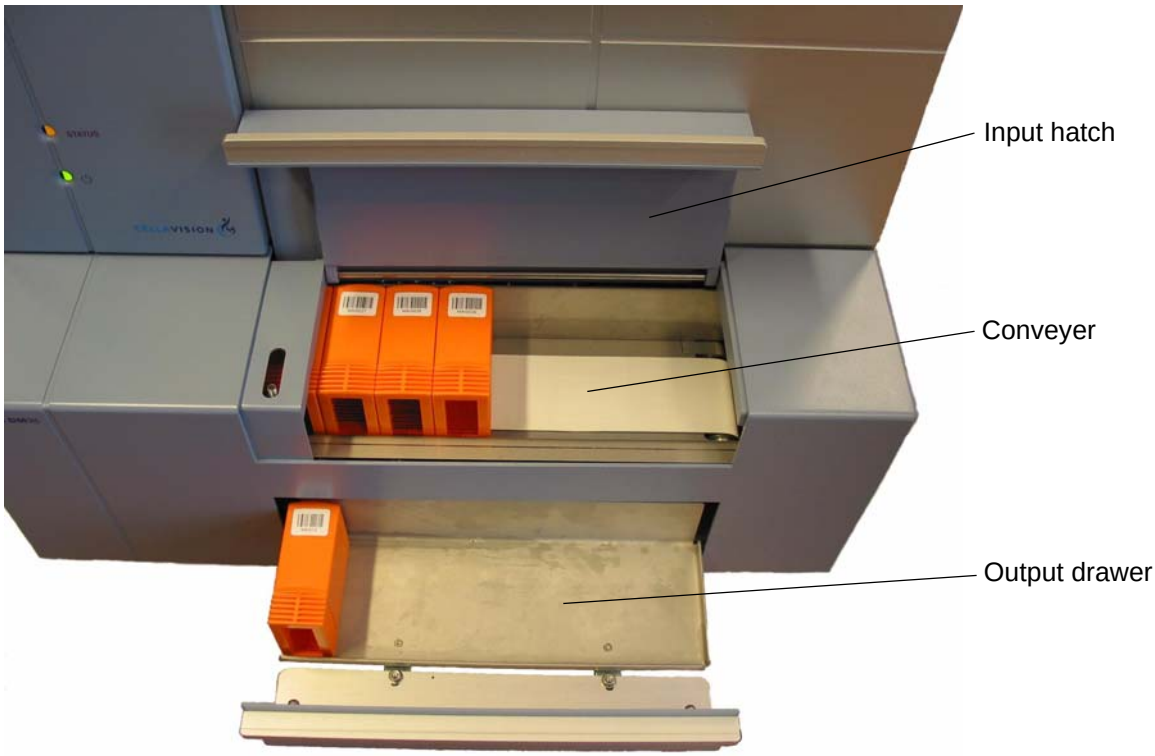
Note! *The same magazine can be used up to 100 times. When this limit is reached a warning is shown.*

Caution

If you want to process an already processed slide, carefully wipe the oil off and make sure the barcode is clean and undamaged.

2.5 Processing Slides

2.5.1 Adding Magazines



Open the input hatch and put the magazines on the conveyer. The magazines must have the barcode turned upwards and the open end of the magazine inwards.

When all slides in a magazine have been processed, the magazine is automatically ejected into the output drawer.

2.5.2 Starting the Slide Processing

Click on the *Start* button to start the slide processing. If you want the processing to start automatically when a magazine is inserted into the system, you can enable autostart in *Analysis Settings*. You still have to manually start the processing if the system has been stopped, restarted or if an error has occurred.

Start button

Autostart - Replaces the Start button.

Stop button

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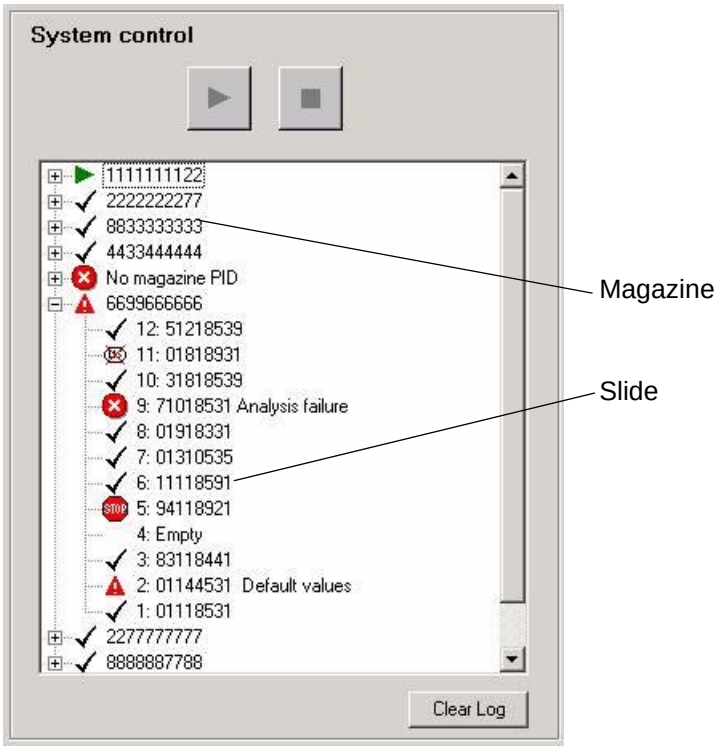
The tree in the *System Control* panel displays a status log of processed magazines and slides.



To empty the log from all information, click *Clear Log*.

2.5.3 Magazine Status

The following information is available for each magazine:

Magazine status	Magazine ID (barcode).
⚠	012345678912

Magazine Status:

▶	Analyzing	
✓	Finished	The slide holder is processed and all slides have status OK.
⚠	Warning	A slide with status Warning, Stopped, Failed or Cancelled exists in the magazine.
⊗	Failed	The magazine has no magazine ID.

2.5.4 Slide Status

The following information is available for each slide:

Slide status	Slide position	Order/Slide ID (barcode)	Error/warning text
	7	012345678912	Default values

Slide Status:

	Processing	
	OK	Slide processed with no warning or error.
	Warning	Slide processed with a warning, see warning texts below. Results exist.
	Stopped	Slide processing stopped by user. No results exist.
	Error	All ordered analyses failed, see error texts below. No results exist.
	Cancelled	The slide was cancelled in the LIS. Slide not processed.
Empty	Empty or no slide PID	Empty slide position in the magazine or no barcode on slide.

Warning Texts:

Default values	The order was not found in the LIS.
Incomplete analysis	The required number of WBCs were not found or one of the ordered analyses failed.

Error Texts:

Invalid slide PID	Invalid barcode on the slide.
Analysis failure	Slide processing failed.
Critical failure	A critical error occurred.

Slide Information Dialog

Double-click on a slide to open the Slide Information dialog. Additional information on the processed slide, e.g. the cause of an error, is displayed here.

2.6 Ejecting Magazines

The slide holder currently being processed can be ejected.

1. Click *Stop*. A *Stop/Continue* dialog appears.
2. Click *Stop*.
3. Select *Eject Magazine* in *Tools* menu. An *OK/Cancel* dialog appears.
4. Click *OK*. The magazine is ejected into the output drawer.

2.7 Handling of STAT Slides

1. Eject the magazine.
2. Load the STAT slide in slide position 1 in a magazine.
3. Open the input hatch and put the magazine to the left of the other magazines.

Note! *The leftmost magazine can be hard to pull out. Open and close the input hatch and the conveyor will move the magazines to the right.*

4. Click *Start*.

2.8 Shutting Down the System

Shut down the system as follows:

1. Eject any remaining magazine from the system.
2. Select *Exit* in the *File* menu.
3. Switch off the system computer.
4. Switch off the slide scanning unit.

3 Verifying Processed Slides, Peripheral Blood

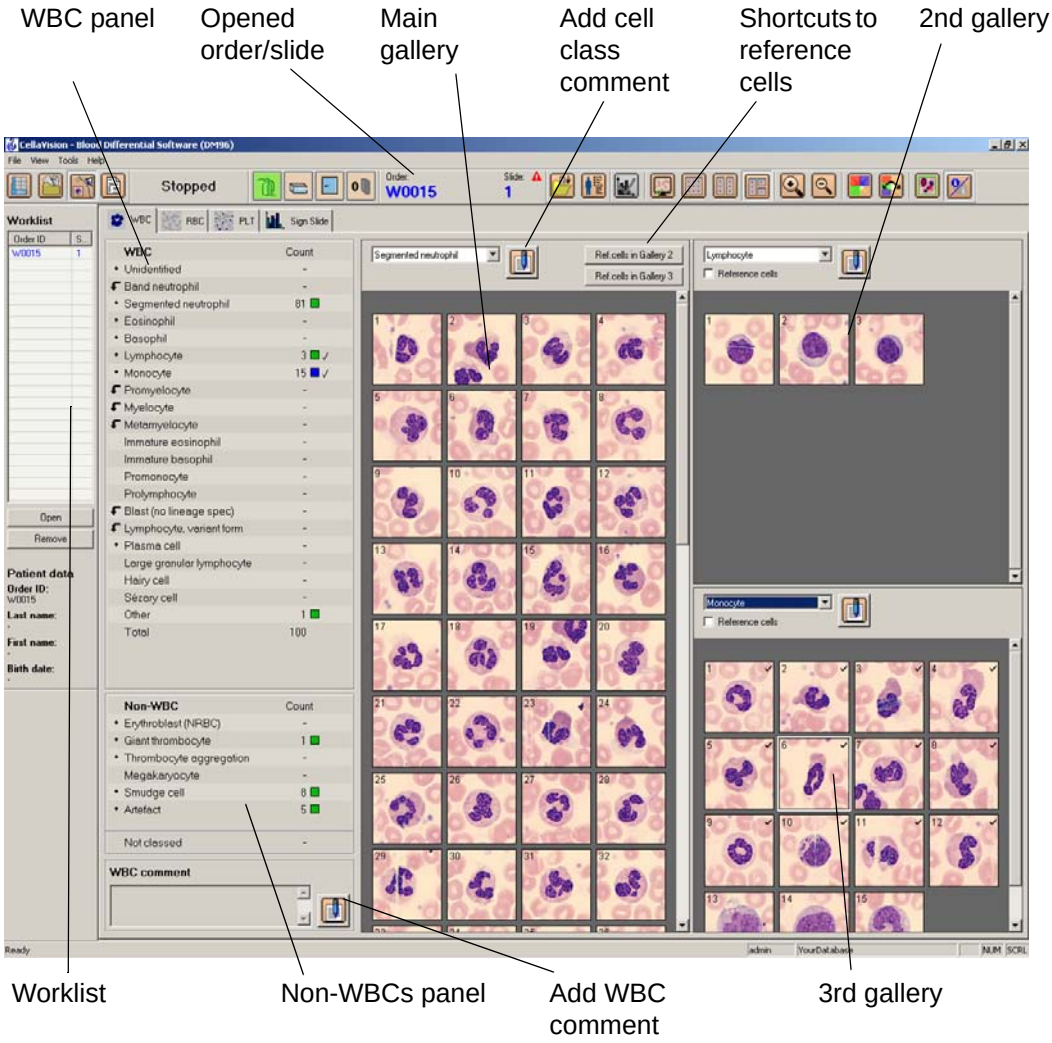
Opening an unsigned slide leads directly to the *Verification View*, where various tabs can be selected in order to review WBC, RBC and PLT and to Sign the Slide. To open a slide, see 6.1.3 Opening an Order/Slide.

Click *Verification View* in the toolbar.

Note! *With DMConfiguration tool it is possible to add user defined WBC cell classes and RBC characteristics. To do this, contact your service personnel.*

3.1 White Blood Cell Classification

You can view all WBCs identified by the system. You may also reclassify WBCs and add comments.



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All cell classes handled by the system are displayed in the figure on the following page. WBCs and non-WBCs automatically preclassified by the system are marked with a small dot or an arrow. In settings (see 10.4 Adjusting Reclassification Settings), you may choose to auto-forward preclassified WBCs to another cell class as follows:

Band neutrophil to *Segmented neutrophil*

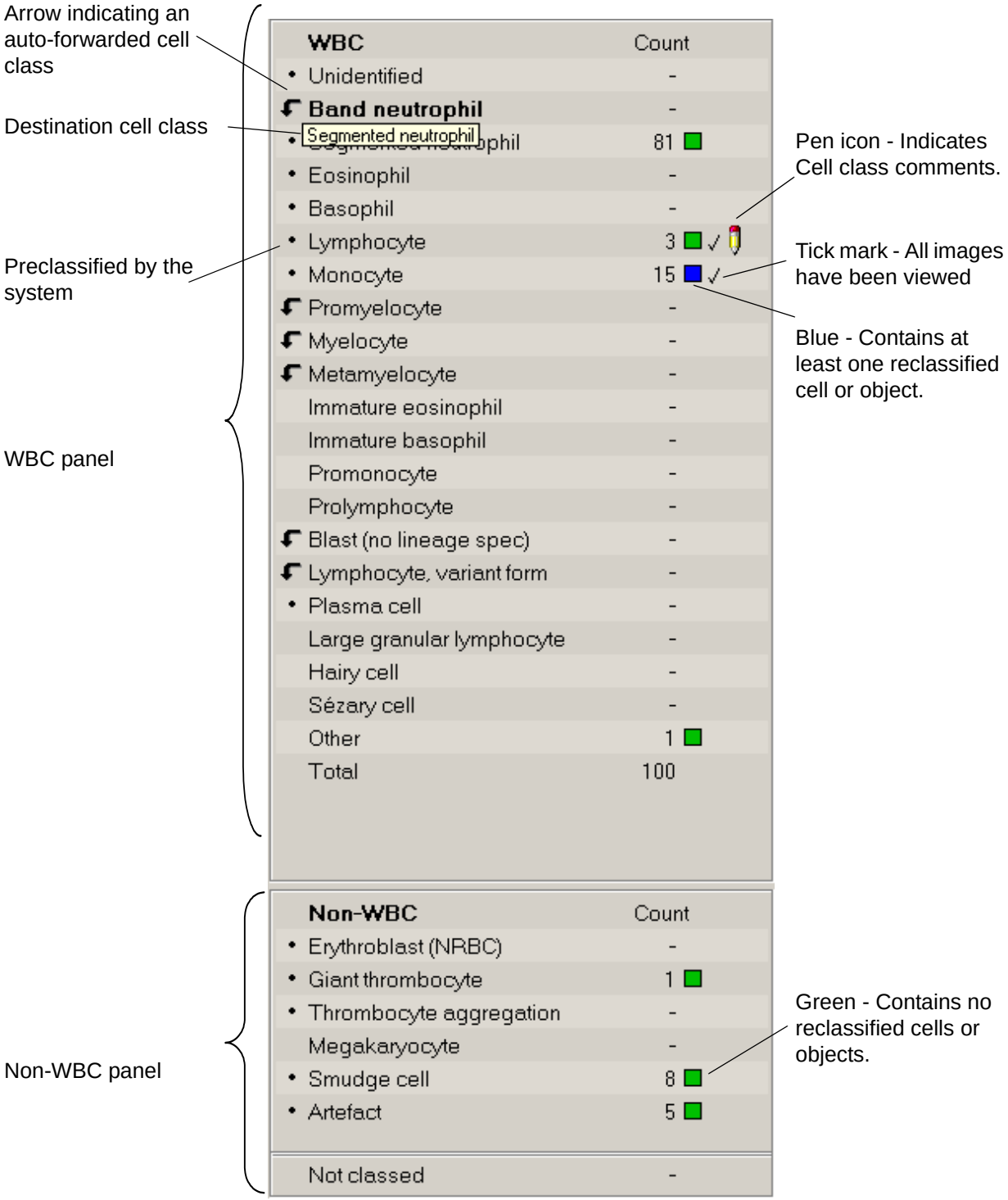
Metamyelocyte to *Segmented neutrophil*

Lymphocyte, variant form to *Lymphocyte*

Plasma cell to *Lymphocyte*

Blast cell, *Metamyelocyte*, *Myelocyte* and *Promyelocyte* to *Other.*

An arrow indicates an auto-forwarded cell class. Place the cursor over the arrow to see the destination cell class.



3.1.1 Customizing Views

Galleries

WBCs are presented, by class, in galleries. The main gallery is always shown together with up to two additional galleries. Click *WBC Galleries* to change the number of galleries.

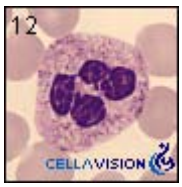
WBC Galleries

Left- and right-clicking in the WBC and Non-WBCs panels also changes cell class in the main and the 2nd gallery, respectively. You can also select cell class in the drop-down list.

The system keeps track of all WBCs viewed by the operator. A tick mark appears when all WBCs of a cell class have been displayed. It is not possible to sign the slide unless all cell classes have been viewed.

Reference Cells

A library of reference cells for different cell classes is provided with the system. These cells are marked with a CellaVision® logo. The main gallery always displays WBCs from the slide, while the other show reference cells when checkbox Reference cells is activated. The main gallery has shortcuts to display reference cells in the other galleries. Click *Ref.cells in Gallery 2* and the 2nd gallery will display reference cells of the cell class selected in the main gallery.



Indicates reference cell provided with the system

You may expand this library by saving WBCs from processed slides as custom reference cells.

1. Right-click on the WBC.
2. Select *Save as custom ref. cell* in the menu.
3. Restart the program.

The WBC will be displayed at the top of the 2nd or 3rd galleries, followed by the reference cells provided with the system. If you want to organize your custom reference cells, see 10.9 Adjusting Reference Cells Settings.

Note! *Reference cells are not available for body fluids.*

(Cont'd)

(Cont'd)

Cell Class Comments

Click *Comment* in the galleries to add a cell class comment. A pen icon will appear to the right in the *WBC* and *Non-WBC*s panels. Click this icon to view, edit or add more comments (see 3.4 Comments).

WBC Full Screen View

Click *WBC Full Screen View* to display all WBCs sorted by class.

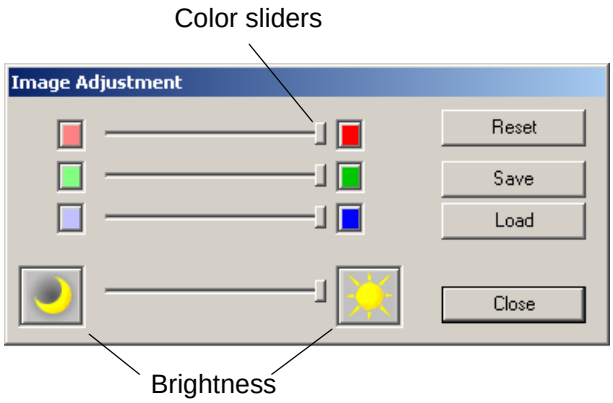
WBC Full Screen View

Note! *Cell classes that have been fully displayed in WBC Full Screen View will also be tick marked.*

Adjusting Image Color and Brightness

Click *Color/Brightness* to display the *Image adjustment* dialog.

Color/Brightness



Color sliders: Changes the color composition of the image.
Brightness: Adjusts the brightness of the image.
Reset: Restores original settings.
Save: Stores individual settings.
Load: Gets individual settings.

(Cont'd)

(Cont'd)

Individual settings can also be switched using *Toggle Color/Brightness*.

Toggle Color/Brightness

Adjusting Magnification

Click *Zoom In* or *Zoom Out* to change the magnification in all galleries and in the *WBC Full Screen View.*

Zoom In

Zoom Out

Note! *You may also double-click on a WBC to enlarge it, and use the wheel button to zoom in/out.*

3.1.2 Reclassifying White Blood Cells

Reclassify WBCs by dragging and dropping them from one gallery to another:

1. Place cursor over the cell image.
2. Click and hold down left mouse button.
3. Move cursor to the destination gallery then release button.

You may also drag and drop cells to the WBC and Non-WBCs panels. Press *Ctrl* or *Shift* to select multiple cells. Reclassified cells always appear at the top of the gallery. A cell class containing at least one reclassified cell is marked blue in the WBC and Non-WBCs panels. If a cell is reclassified to its own cell class, it is considered reclassified and moved to the top of the gallery.

Note! *You can never reclassify WBCs on a signed slide.*

(Cont'd)

(Cont'd)

Splitting Cells

If more than one cell is displayed in an image it can be difficult to determine which cell the system has actually identified. Click *Cell Marker* and a green square appears, marking the cell.

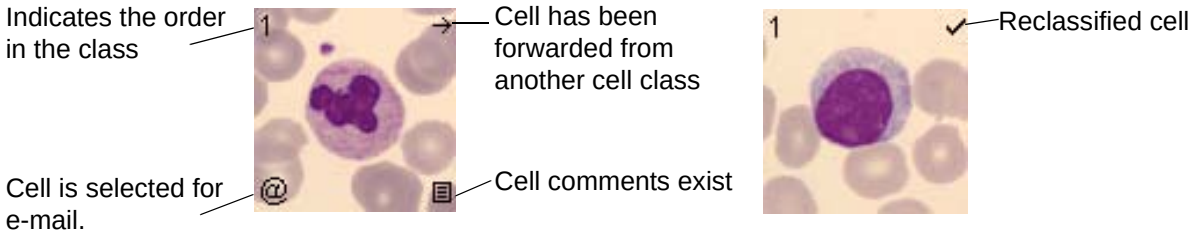
Cell Marker

Sometimes the system fails to separate WBCs and the green square will cover more than one cell. It is now possible to split cells using the right-click menu and select *Split cell*. A dialog appears explaining the procedure. Split cells are always moved to the bottom of the gallery. The green square is never changed for split cells. Instead, if you click on *Cell Marker*, a red cross marks the cell.

Note! *Cells created by splitting can always be removed, using the right-click menu.*

WBC Attributes

Each cell is associated with attributes.


Indicates the order in the class
Cell is selected for e-mail.
Cell has been forwarded from another cell class
Cell comments exist
Reclassified cell

WBC attributes are shown by default. Click *WBC Attributes* to show/hide them.

WBC Attributes

(Cont'd)

(Cont'd)

Right-click Menu

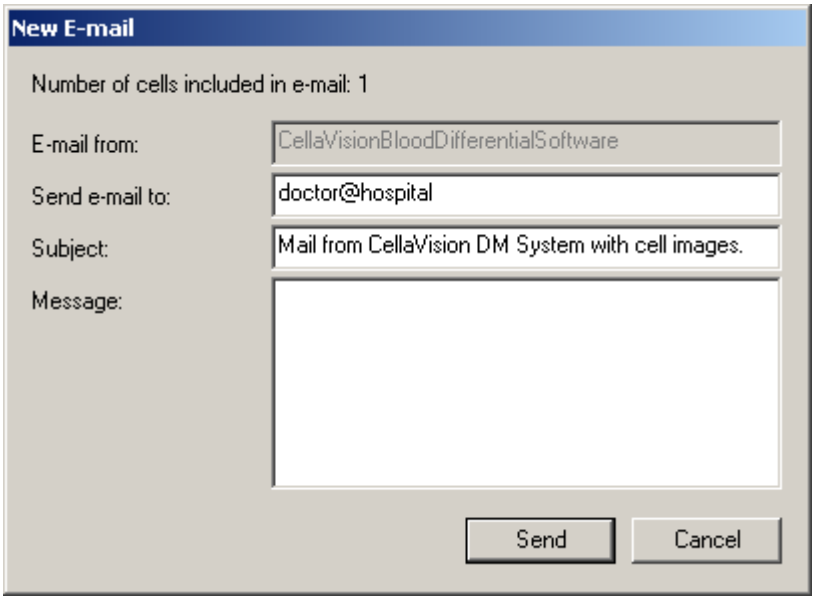
Right-click on a cell to set/view attributes. A menu appears, allowing the following options:

1. *View DM's 1st, 2nd and 3rd suggestions of classification.*
2. *Reclassify cell.*
3. *Add/view cell comments* (see 3.4 Comments).
4. *Split cell* or *remove split cell.*
5. *Select cell for e-mail.*
6. *Save cell as custom reference cell.*
7. *Save images to disk.*

3.1.3 E-mail

You may send cell images by e-mail.

1. Select *select for e-mail*, using the right-click menu.
2. Select *Tools/Send E-mail* and the *New E-mail* dialog appears.



For default values, see *E-mail* tab in *Settings*.

3. If desired, change receiver address.
4. If desired, add *Subject* and *Message*.
5. Click *Send*.

Note! *You may only send cells from one slide in each e-mail.*

3.1.4 Copying Images to Disk

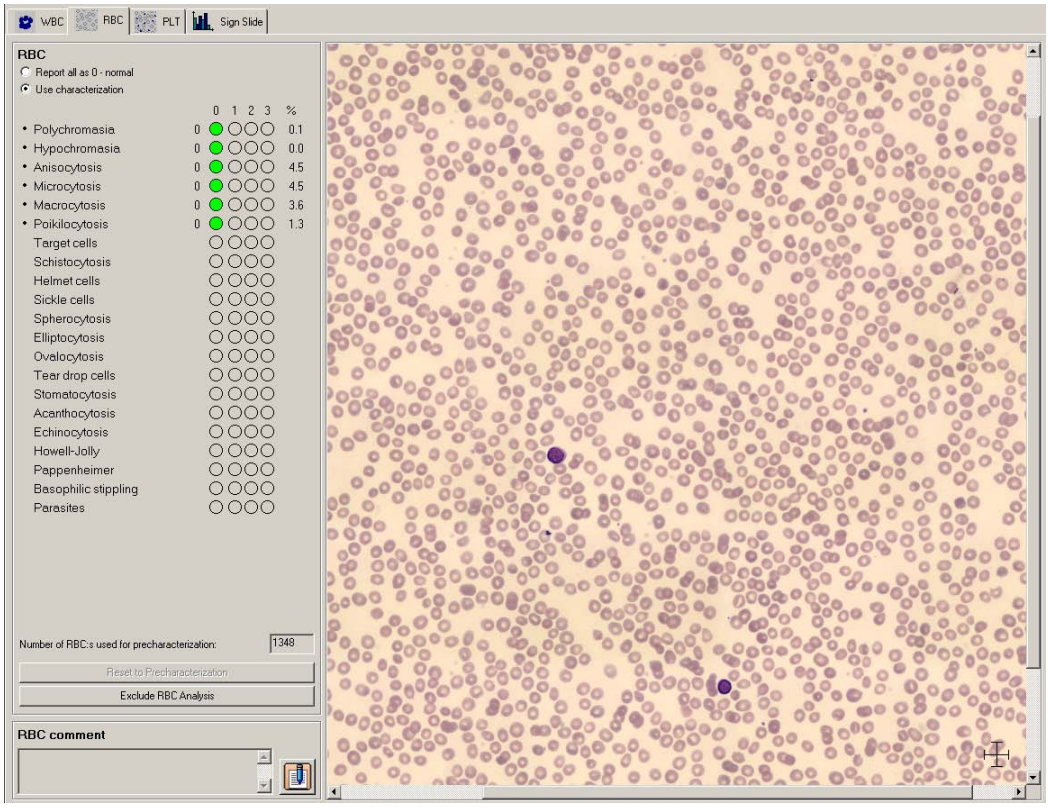
You may copy selected images to disk.

1. Select cells for copying.
2. In the right-click menu select *Copy images to disk*… and the *Copy images to disk* dialog appears.
3. Specify the destination path where you want the images to be saved.
4. Click *OK*.

Note! *The directory you specify in the destination path must exist.*

3.2 Red Blood Cell Characterization

The RBC overview image corresponds to the area of 8 microscopic high power fields (HPF) (100x objective and a 22mm ocular). See 10.5 Adjusting RBC Precharacterization Settings.



The RBC panel is used for characterization of the RBC morphology. All morphologies handled by the system are listed. Morphologies precharacterized by the system are marked with a small dot.

(Cont'd)

(Cont'd)

The columns labeled 0 to 3 grade the morphology characteristics.

Normal	Green dot in column 0 indicates a normal level.
Slight	Red dot in column 1 indicates that the morphology is present at a low level.
Moderate	Red dots in column 1-2 indicate that the morphology is present at a moderate level.
Marked	Red dots in column 1-3 indicate that the morphology is present at a high level.

The rightmost column shows the percentage of RBCs in the overview image with the characteristic in question. If the precharacterization is overridden by manual characterization, the percentage is shown dimmed.

In the bottom right-hand corner of the RBC image there is a cross-shaped ruler that represents 14 µm across. As the image magnification is increased, numbers will appear at the ends of the ruler to indicate the scale in micrometers. The ruler can be moved around the RBC image by moving the mouse pointer (in either zoom mode or scroll mode) over the ruler, depressing the left mouse button and then by dragging it to its desired placement.

The ruler will be placed back in the bottom right corner whenever the view is changed.

The ruler shape can be toggled between the default cross shape and a line shape by double-clicking on it. The shape will not change back to the cross when shifting views.

A thin window frame appears around the ruler when the mouse pointer is moved over it to indicate that the ruler can be moved or have its shape changed.

3.2.1 Customizing the Red Blood Cell Overview Image

Change the magnification of the image by using these buttons:

Zoom In

Zoom Out

Entire RBC Image - Shows the entire RBC image.

Navigate the image by switching between different control modes. The mouse pointer changes accordingly.

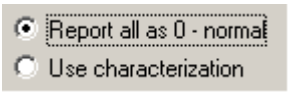
Zoom Mode - Hold left mouse button down and zoom in/out by moving the mouse pointer up/down.

Scroll Mode - Hold left mouse button down and scroll in any direction using the mouse.

Note! *You may also double-click in the RBC image to enlarge a limited area, and use the wheel button to zoom in/out.*

3.2.2 Characterizing Red Blood Cell Morphology

There are two ways to report the RBC result:



a) Report all as normal

1. Select radio button *Report all as 0 - Normal*.

b) Use characterization

1. Select radio button *Use characterization*.
2. If you disagree with a precharacterization, click the dot that corresponds to your opinion.

Click *Reset to Precharacterization* to restore the precharacterization result done by the system. All manual characterization will be lost.

Note! *If you want to remove a specific type of morphology from the report, deselect the dot by clicking on it.*

3.2.3 Excluding the Red Blood Cell Analysis

Click *Exclude RBC Analysis* to exclude the RBC analysis results from the slide.

3.3 Estimating Platelets

The complete PLT overview image (same image as for RBC) corresponds to the area of 8 microscopic high power fields (HPF) (100x objective and a 22mm ocular). The overview image is divided into 4, 9 or 16 sub-images (grid squares) as defined by the grid size. The grid size options are 2x2, 3x3 and 4x4. The 4x4 grid size gives the largest magnification of the image. There are as many entry fields as there are grid squares.

By clicking *Help Lines* in the toolbar, a grid of lines is drawn over the image to facilitate the counting of PLTs.

There are two ways, or modes to perform the PLT estimation. This is determined in PLT settings (see 10.6 Adjusting PLT Settings).

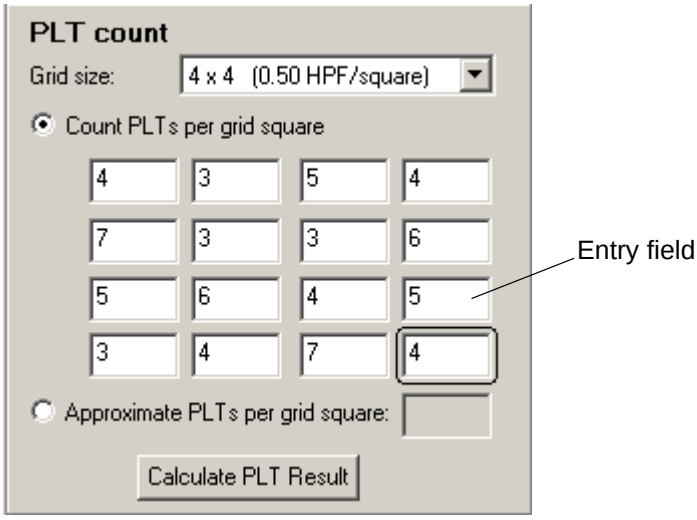
1. Counting PLTs in the overview image
2. Estimating the PLT concentration level

Note! *When a slide is opened for the first time, the slide gets mode according to the settings and the mode can then not be changed for that order. The system ensures that all slides in a multi-slide order have the same mode.*

3.3.1 Counting Platelets in the Overview Image

PLT Count

The estimation of the PLT concentration is based on the number of PLTs, which must be counted manually. You can choose to count the number of PLTs in each grid square or to specify an approximate number of PLTs per grid square.



a) Counting PLTs per grid square

1. Select the *Count PLTs per grid square* radio button.
2. Select the entry fields one by one, count the PLTs in the image window and type the number in the entry field. You can use tab and *Shift+Tab* to move between entry fields.

b) Specifying an approximate PLT count per grid square

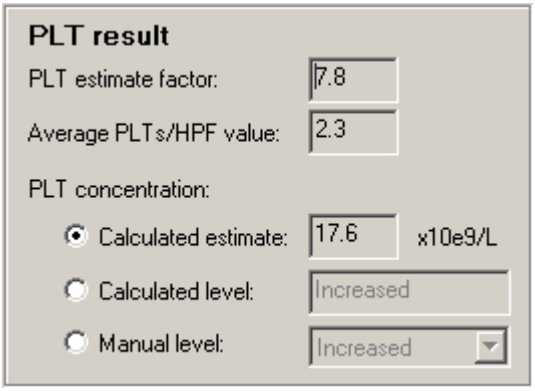
1. Select the *Approximate PLTs per grid square* radio button.
2. Use the entry fields to view different grid squares.
3. Estimate the average PLT count per grid square and type this value in the field.

(Cont'd)

(Cont'd)

PLT Result

1. Click *Calculate PLT Result* in the *PLT Count panel*.



2. If you wish to report the PLT results calculated from the number of PLTs per HPF, you have two choices:
   - Select *Calculated estimate* to report a concentration. The estimate is calculated as [Average PLTs/HPF value] x [PLT estimate factor].
   - Select *Calculated level* to report one of four levels: S*ignificantly decreased, Decreased, Normal* or *Increased*.
3. If you wish to override the calculated PLT results, select *Manual level* and choose one of the four levels.

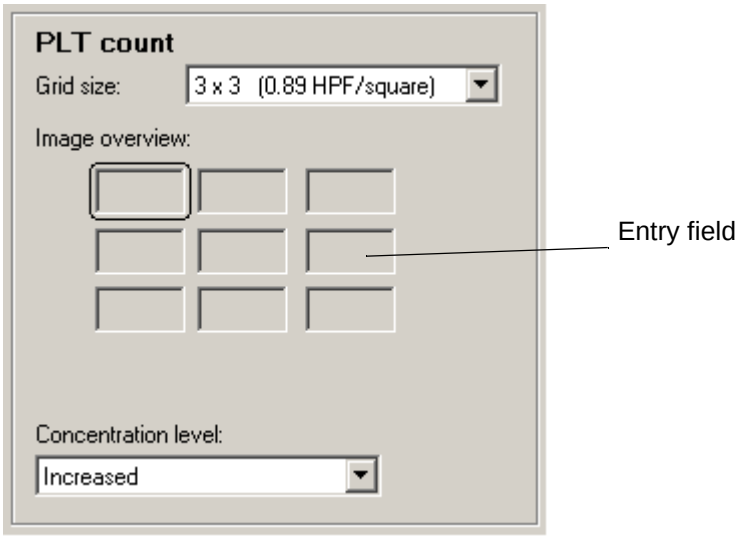
Important

You have to determine your own PLT estimate factor and enter it in PLT settings. By default, it is set to "0".

Note! *In the calculations, several decimals are used. The presented results are truncated to 1 decimal, which means that the results may seem incorrect.*

3.3.2 Estimating the Platelet Concentration Level

The PLT concentration level can be estimated by setting it to four levels: *Significantly decreased*, *Decreased*, *Normal* or *Increased* directly from viewing the image.



1. Use the entry fields to view all parts of the overview image.
2. Select *Concentration level*.

3.3.3 Excluding the Platelet Analysis

Click *Exclude PLT Analysis* to exclude PLT analysis results from the slide.

3.4 Comments

For each slide, you can add comments to the WBC, RBC and PLT results. For WBC analyses, you can also add comments to cell classes and individual cells.

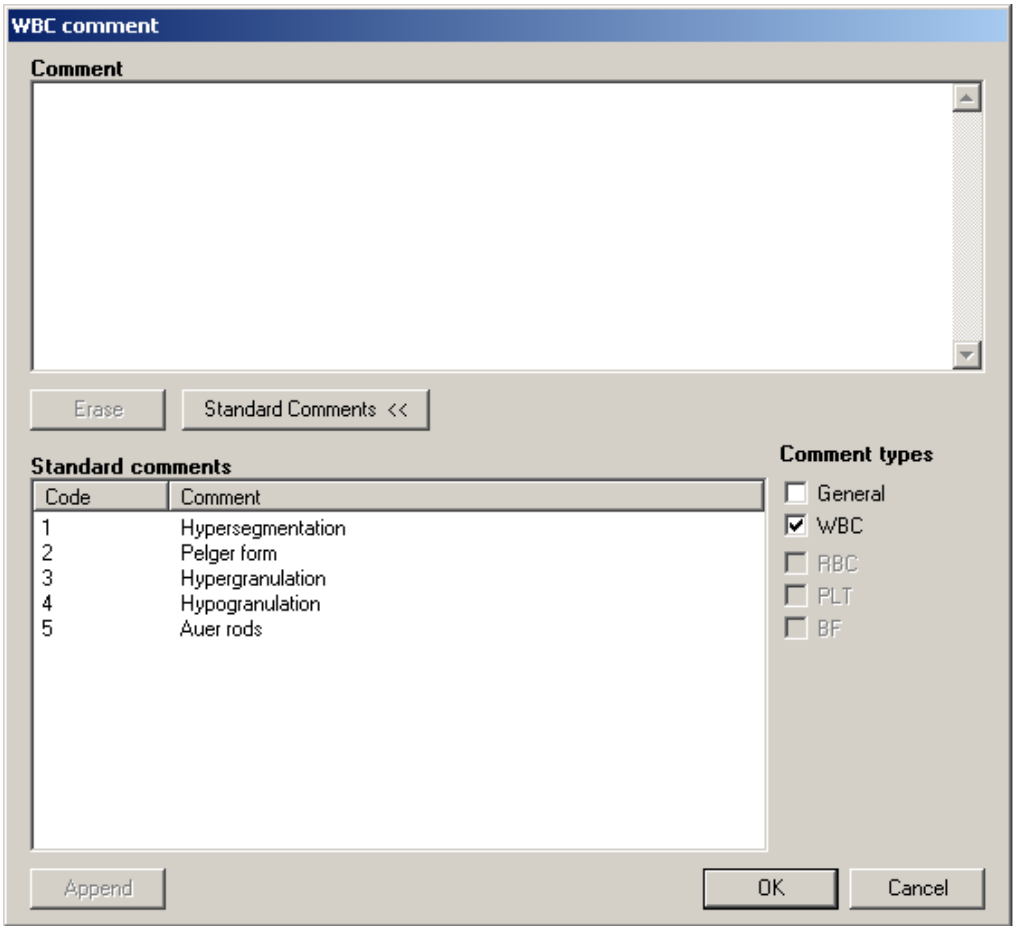
WBC, RBC and PLT comments are added in *Verification View* in each tab respectively. Cell class and cell comments are added in the *WBC tab* in *Verification View.*

Note! *All comments, except comments on individual cells, are printed in the report.*

3.4.1 Adding Comments

The system records the author of each comment, except for comments to cell classes and individual cells. If another operator logs in, each comment is tagged with the name of the operator who wrote it. An operator can view all comments but can only edit his/her own.

Click *Comments* to add comments to WBC, RBC and PLT.



You may write/edit comments in the *Comment* box. Click *Standard Comments* to show/hide standard comments. Double-click on a standard comment to add it to the *Comment* box. You may also select a standard comment and click *Append*.

(Cont'd)

(Cont'd)

You may activate the Comment types you want to display. Standard comments of type WBC, RBC or PLT will only be available in the respective tab. Standard comments can be added and edited in *Settings*, see 10.8 Adjusting Standard Comments Settings.

To clear comments, click *Erase*.

3.5 Order Data

To edit order data, click *Order Data* in the toolbar.

A dialog is shown containing information about the open order. If no data is received from the LIS it is possible to edit some of the information. The Order ID can only be edited if it starts with 'ER'.

The *Order Data* dialog can also be accessed by right-clicking on an order in the database view.

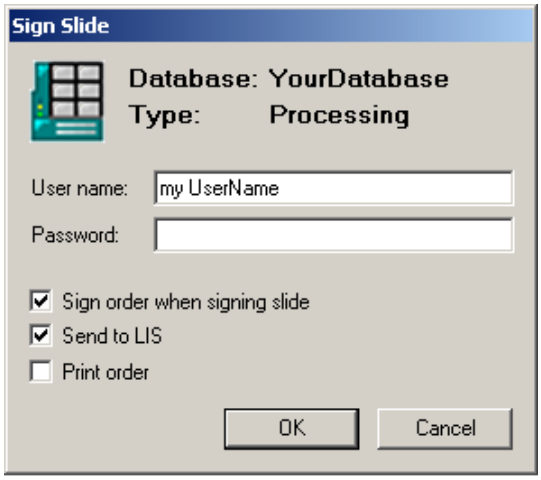
If you can't generate barcode labels (printer is broken, out of printer ribbon, or out of labels) you can use pre-printed labels with the prefix 'ER' (available through your local dealer).

3.6 Signing a Slide

A summary of the WBC, RBC and PLT analyses is presented in the *Sign Slide* tab.

The signing procedure is as follows:

1. Click *Sign*. The *Sign Slide* dialog appears.



2. Enter *User name* and *Password*.
3. Activate/deactivate the automatic options *Sign order when signing slide*, *Send to LIS* and *Print order.*
4. Click *OK*.

Note! *If the slide is part of a multi-slide order, all slides in the order must be signed before the operator is given the option to sign the order.*

Note! *Slide data cannot be changed after signing. Comments may still be added.*

If all ordered analyses have been viewed when the *Sign Slide* tab is selected, the *Sign Slide* dialog will automatically appear. Default values for the *Sign Slide* dialog are set in *Settings* under *Report/Sign*. The option to send results to the LIS is activated in *Analysis* in *settings*.

When the last slide is signed in a multi slide order, the operator has the option to sign the order.

3.6.1 White Blood Cells, Red Blood Cells and Platelets

Before signing a slide, all ordered analyses must have been viewed by the operator. The following conditions must be fulfilled:

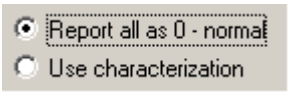
WBC

- All cell classes must have been viewed, i.e. there should be tick marks after each cell class.
- No WBCs remain in *Unidentified*.

RBC

An RBC characterization must be reported or excluded from the analysis:

Report a characterization, by selecting one of the following options:



OR:

- Click *Exclude RBC Analysis*.

PLT

A PLT concentration must be reported or excluded from the analysis:

- Report a PLT concentration as described in 3.3 Estimating Platelets.

OR:

- Click *Exclude PLT Analysis*.

4 Verifying Processed Slides, Body Fluids

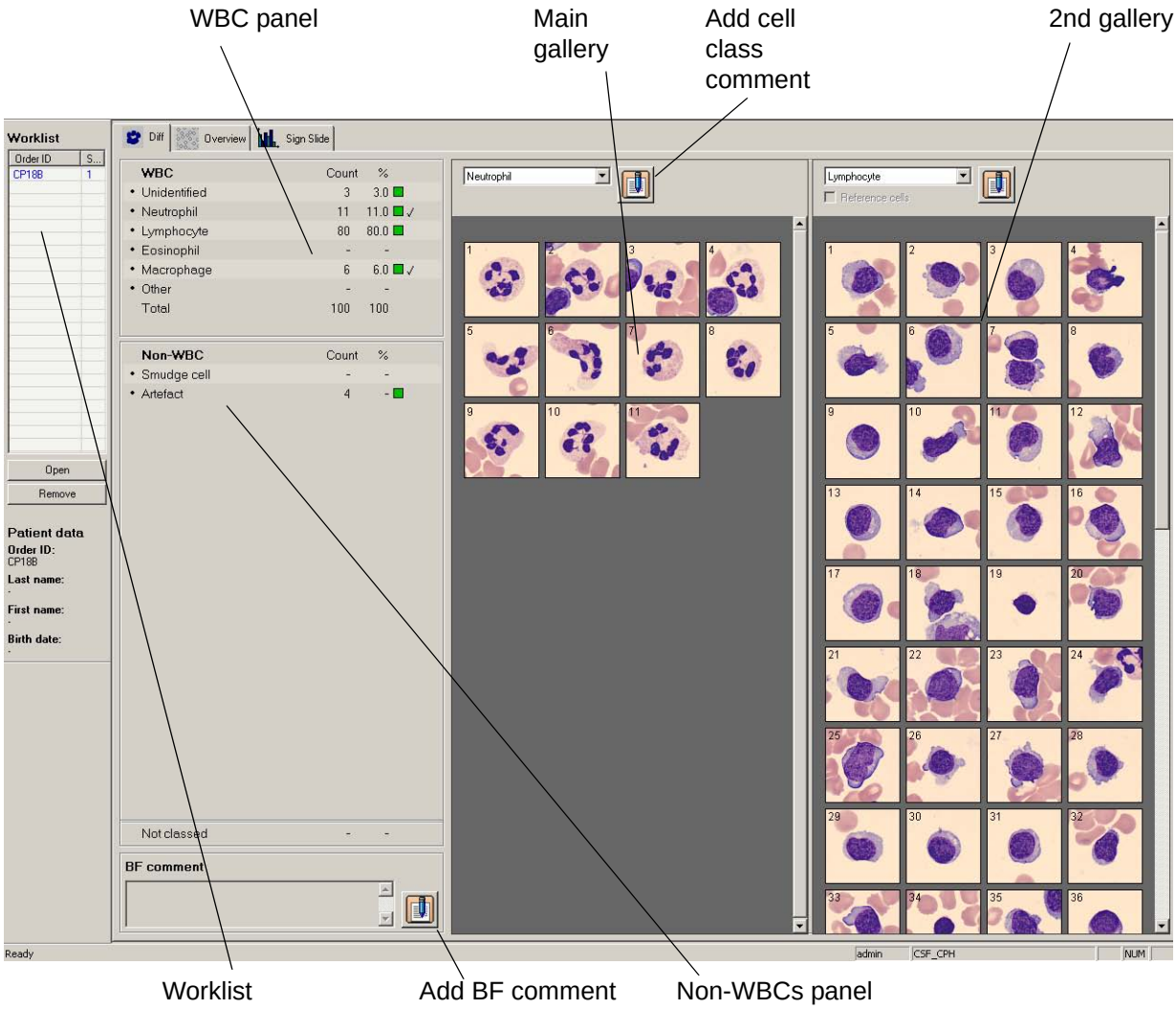
Opening an unsigned slide leads directly to the Verification View, where the tabs for *Overview, WBC* and *Sign Slide* are shown. To open a slide, see 6.1.3 Opening an Order/Slide.

Click *Verification View* in the toolbar.

Note! *With DMConfiguration tool it is possible to add user defined WBC cell classes and Non-WBC classes. To do this contact your service personnel.*

4.1 Body Fluids Differential

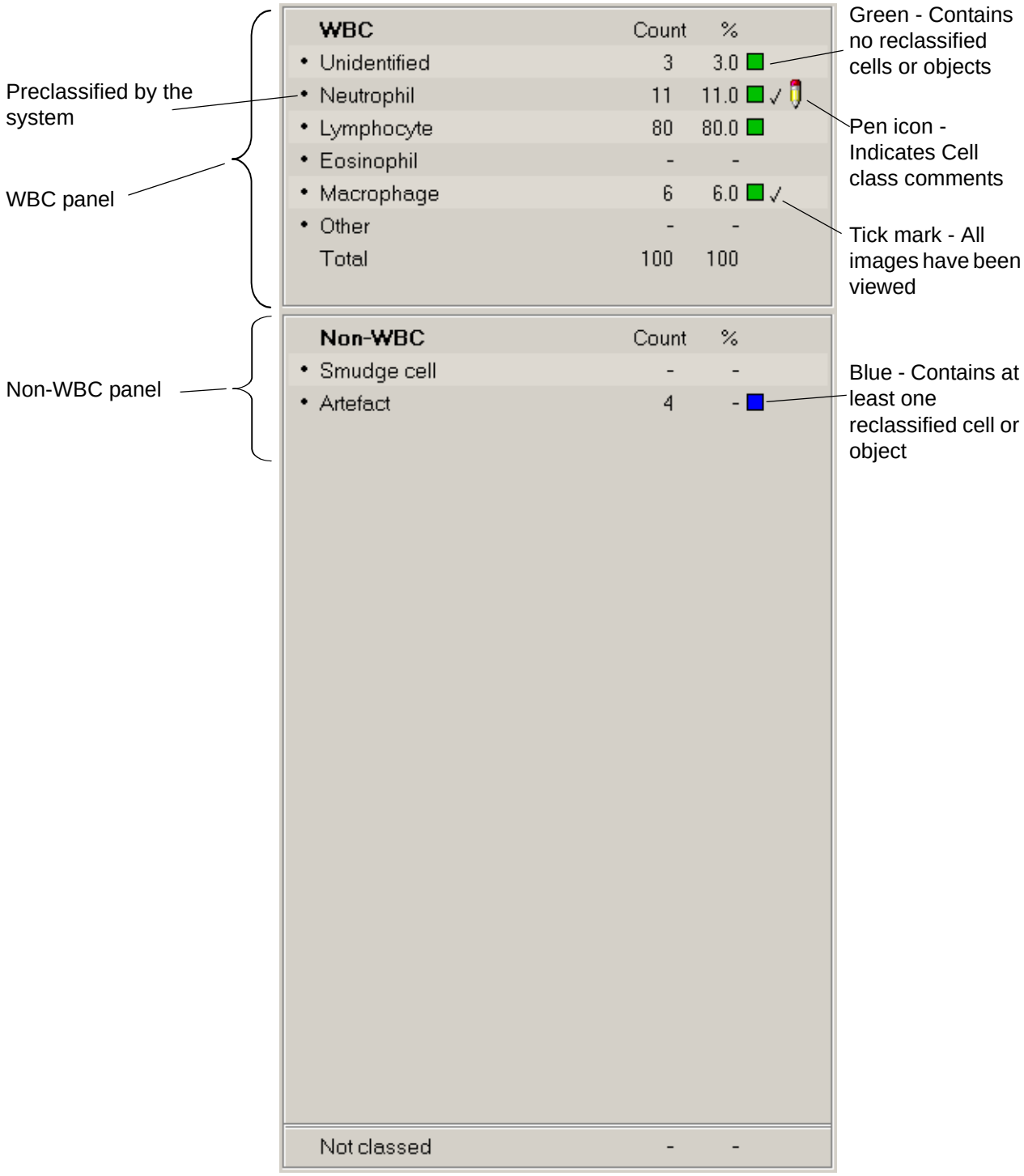
You can view and reclassify all cells identified by the system.



(Cont'd)

(Cont'd)

All cell classes handled by the system are displayed in the figure below. WBCs and non-WBCs automatically preclassified by the system are marked with a small dot.


Preclassified by the system
WBC panel
Non-WBC panel
WBC Count %
Unidentified 3 3.0
Neutrophil 11 11.0
Lymphocyte 80 80.0
Eosinophil - -
Macrophage 6 6.0
Other - -
Total 100 100
Non-WBC Count %
Smudge cell - -
Artefact 4 -
Not classed - -
Green - Contains no reclassified cells or objects
Pen icon - Indicates Cell class comments
Tick mark - All images have been viewed
Blue - Contains at least one reclassified cell or object

4.1.1 Customizing Views

To Customize views, see 3.1.1 Customizing Views.

4.1.2 Reclassifying Cells

To reclassify cells, see 3.1.2 Reclassifying White Blood Cells.

4.1.3 E-mail

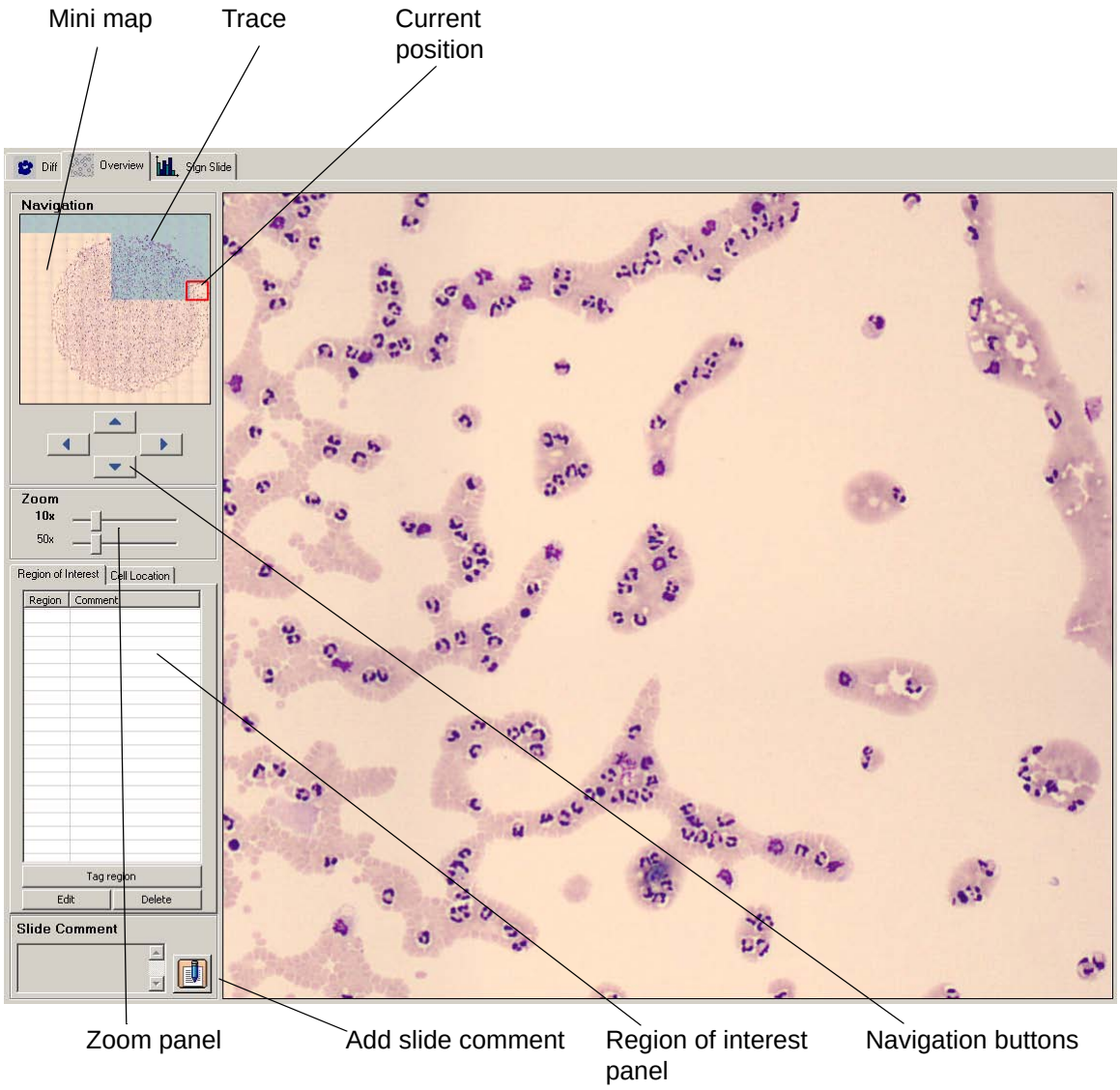
To email cell images, see 3.1.3 E-mail.

4.1.4 Copying Images to Disk

To copy cell images, see 3.1.4 Copying Images to Disk.

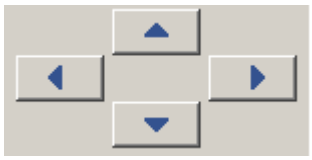
4.2 Body Fluids Overview Image

The body fluid overview image displays the entire sample area (see 10.13 Adjusting BF Analysis Area). The overview image can be used to find cells of interest and for getting an overall impression of the sample. The overview image can either have one 10x zoom level or both 10x and 50x zoom levels. Using both zoom levels will increase the processing time (see 10.3 Adjusting Analysis Settings).



4.2.1 Navigating in the Overview Image

Navigate in the overview image by using the keyboard arrow buttons or the navigation buttons.



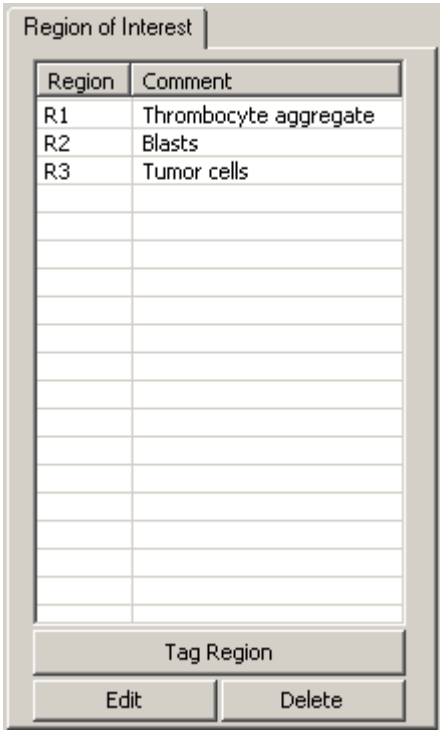
The image shown in the right part of the screen is an enlargement of the area inside the red rectangle shown in the *Mini map*. Click on the *Mini map* to enlarge another part of the sample. A blue trace in the *Mini map* indicates which parts of the overview image that have been viewed by the operator.

Hold left mouse button down and scroll in any direction using the mouse.

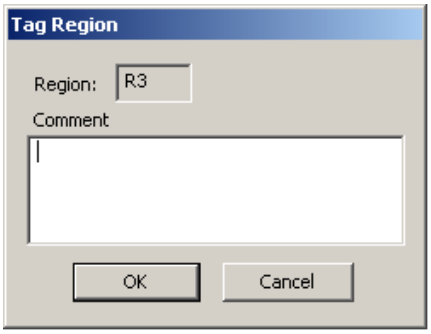
Switch between the two zoom levels by right-clicking in the overview image. Adjust the zoom level by dragging the sliders in the *Zoom* panel.

4.2.2 Tagging Regions of Interest

The image shown in the right part of the screen can be saved as a region of interest for later reference.



1. To save the current image, click *Tag region.*
2. Add a comment as an identifier for the region of interest and click *OK*.



4.2.3 Copying Regions of Interest to Disk

You can copy an individual region of interest image to disk.

1. Select a region of interest.
2. On the right-click menu select *Copy image to disk*… and the *Copy the image to disk* dialog appears.
3. Specify the destination path where you want the image to be saved.
4. Click *OK*.

Note! *The directory you specify in the destination path must exist.*

4.3 Comments

Comments can be added to the Overview, the differential result, each cell class and all individual cells.

Note! *All comments, except comments on individual cells, are printed in the report.*

4.3.1 Adding Comments

To add a comment, click *Comment*. For more details, see 3.4.1 Adding Comments.

Comments

4.4 Order Data

To view or edit the order data, see 3.5 Order Data.

4.5 Signing a Slide

The Body Fluid differential is presented in the *Sign slide* tab. To sign a slide, see 3.6 Signing a Slide.

5 Reporting Results

See 10.7 Adjusting Report/Sign Settings for Report/Sign settings.

Click *Report View* in the toolbar.

In the *Report View* you compare the results of each slide in the order and you can exclude slides from the reported result. You sign the order, send order data to the LIS and cancel an order. You can also write a general comment on the order.

5.1 Merging Slides

In the *Slide Merge* tab you compile analysis results for the whole order based on one or several slides. You can also look at all comments associated with an order.

Result Panel

Result

	MT Order 120 (1)	MT Order 120 (2)	Reported Result
WBC			
Unidentified			
Band neutrophil	4.2%	1.9%	4.2%
Segmented neutrophil	22.0%	25.6%	22.0%
Eosinophil	15.3%	11.3%	15.3%
Basophil	5.1%	3.8%	5.1%
Lymphocyte	16.1%	13.1%	16.1%
Monocyte	14.4%	10.6%	14.4%
Promyelocyte			
Myelocyte	1.7%	1.3%	1.7%
Metamyelocyte	3.4%	6.9%	3.4%
Immature eosinophil	4.2%	3.1%	4.2%
Immature basophil	5.1%	7.5%	5.1%
Promonocyte		1.9%	
Prolymphocyte		3.8%	
Blast (no lineage spec)			
Lymphocyte, variant form			
Plasma cell	2.5%	1.9%	2.5%
Large granular lymphocyte			
Hairy cell	1.7%	1.9%	1.7%
Sézary cell	2.5%	1.9%	2.5%
Other	1.7%	3.8%	1.7%
Non-WBC			
Erythroblast (NRBC)	5.1%	3.8%	5.1%
Giant thrombocyte		2.5%	
Thrombocyte aggregation		3.1%	
Megakaryocyte		3.8%	
Smudge cell		1.3%	
Artefact		2.5%	
Not classed			

Here you see the results of each slide in the order. In the *Reported Result* column you see the summarized results. An unsigned slide has a Slide ID written together with slide number in cerise color.

(Cont'd)

(Cont'd)

Including/Excluding Slides in/from the Reported Result

When a slide is signed, it is automatically included in the reported result. To include/exclude a slide, activate/deactivate the checkbox next to the Slide ID. When a slide is excluded, a dialog is shown where you may write a comment explaining the exclusion.

Note! *It is only possible to include signed slides.*

Note! *It is not possible to merge slides if one or more slides have a "confirm cell counter result" flag. The calculated result in the reported result column will be displayed incorrectly.*

Changing the Reported Result

It is possible to change the RBC results and the PLT concentration, if reported as a level, for the order. Results that can be changed are written in bold text.

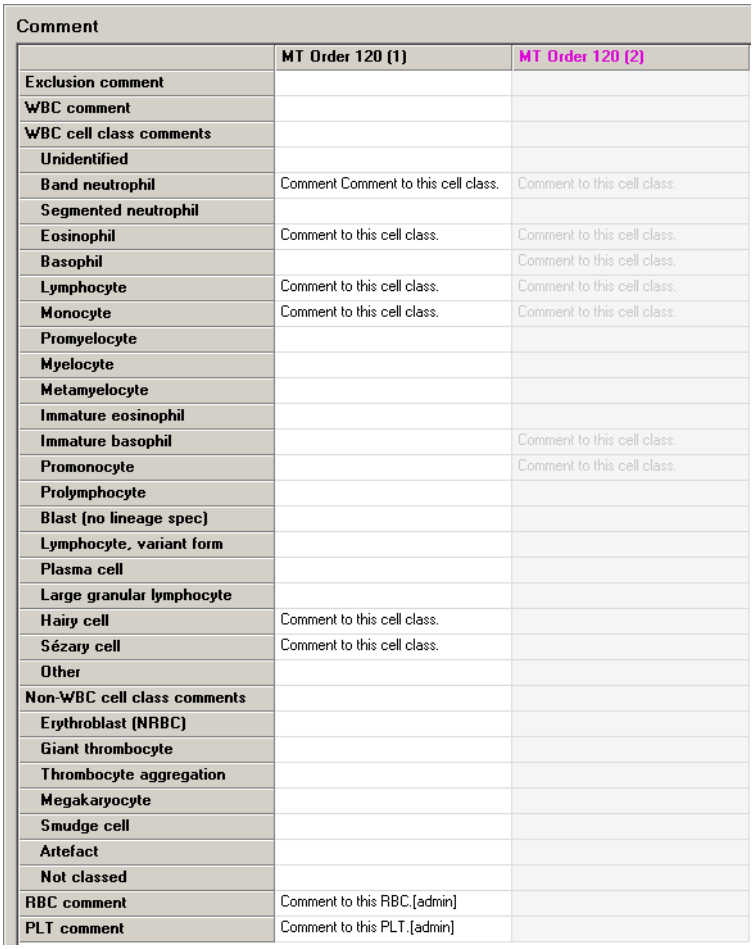
1. Click on the result to change.
2. Change the value in the dialog and click *OK*.

Note! *If you include or exclude a slide, all manually changed values will be replaced by new automatically calculated values.*

(Cont'd)

(Cont'd)

Comment Panel



Comment

	MT Order 120 (1)	MT Order 120 (2)
Exclusion comment		
WBC comment		
WBC cell class comments		
Unidentified		
Band neutrophil	Comment Comment to this cell class.	Comment to this cell class.
Segmented neutrophil		
Eosinophil	Comment to this cell class.	Comment to this cell class.
Basophil		Comment to this cell class.
Lymphocyte	Comment to this cell class.	Comment to this cell class.
Monocyte	Comment to this cell class.	Comment to this cell class.
Promyelocyte		
Myelocyte		
Metamyelocyte		
Immature eosinophil		
Immature basophil		Comment to this cell class.
Promonocyte		Comment to this cell class.
Prolymphocyte		
Blast (no lineage spec)		
Lymphocyte, variant form		
Plasma cell		
Large granular lymphocyte		
Hairy cell	Comment to this cell class.	
Sézary cell	Comment to this cell class.	
Other		
Non-WBC cell class comments		
Erythroblast (NRBC)		
Giant thrombocyte		
Thrombocyte aggregation		
Megakaryocyte		
Smudge cell		
Artefact		
Not classed		
RBC comment	Comment to this RBC.[admin]	
PLT comment	Comment to this PLT.[admin]	

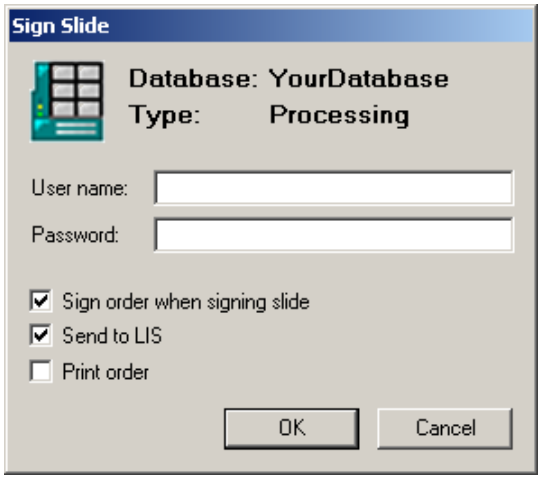
Here you see all comments associated with the order. Only the beginning of the comment is shown in the table. Click on a comment to view the whole comment text. It is not possible to edit comments in this panel. All comments in the *Comment* panel will be included in the report.

5.2 Report Preview

This tab contains a preview of the report. The format of the report is based on templates and these can be selected in *Settings* (see 10.7 Adjusting Report/Sign Settings).

5.3 Signing an Order (result)

1. Click *Sign Order.*



2. Type *Username* and *Password* (if not prefilled).
3. Select whether order shall be sent to the LIS and/or printed.
4. Click *OK*.

Note! *No order data can be changed after signing. Comments may still be added.*

5.4 Sending an Order to the LIS

If the LIS is activated in the *Analysis* tab in *Settings*, it is possible to send signed order results to the LIS.

1. Open a signed order.
2. Select the *Slide Merge* tab in the *Report* View.
3. Click *Send to LIS*.

5.5 Canceling an Order

To cancel an order you sign the order with no included slides. When the order is sent to the LIS the order will be reported as cancelled.

1. Open the order in the *Database* View.
2. Select the *Slide Merge* tab in the *Report* View.
3. Make sure no slides are included.
4. Click *Sign Order*. The *Sign Order* dialog appears.
5. Sign the order as described in 5.3 Signing an Order (result) .

6 Database and Archiving Data

Click *Database View* in the toolbar.

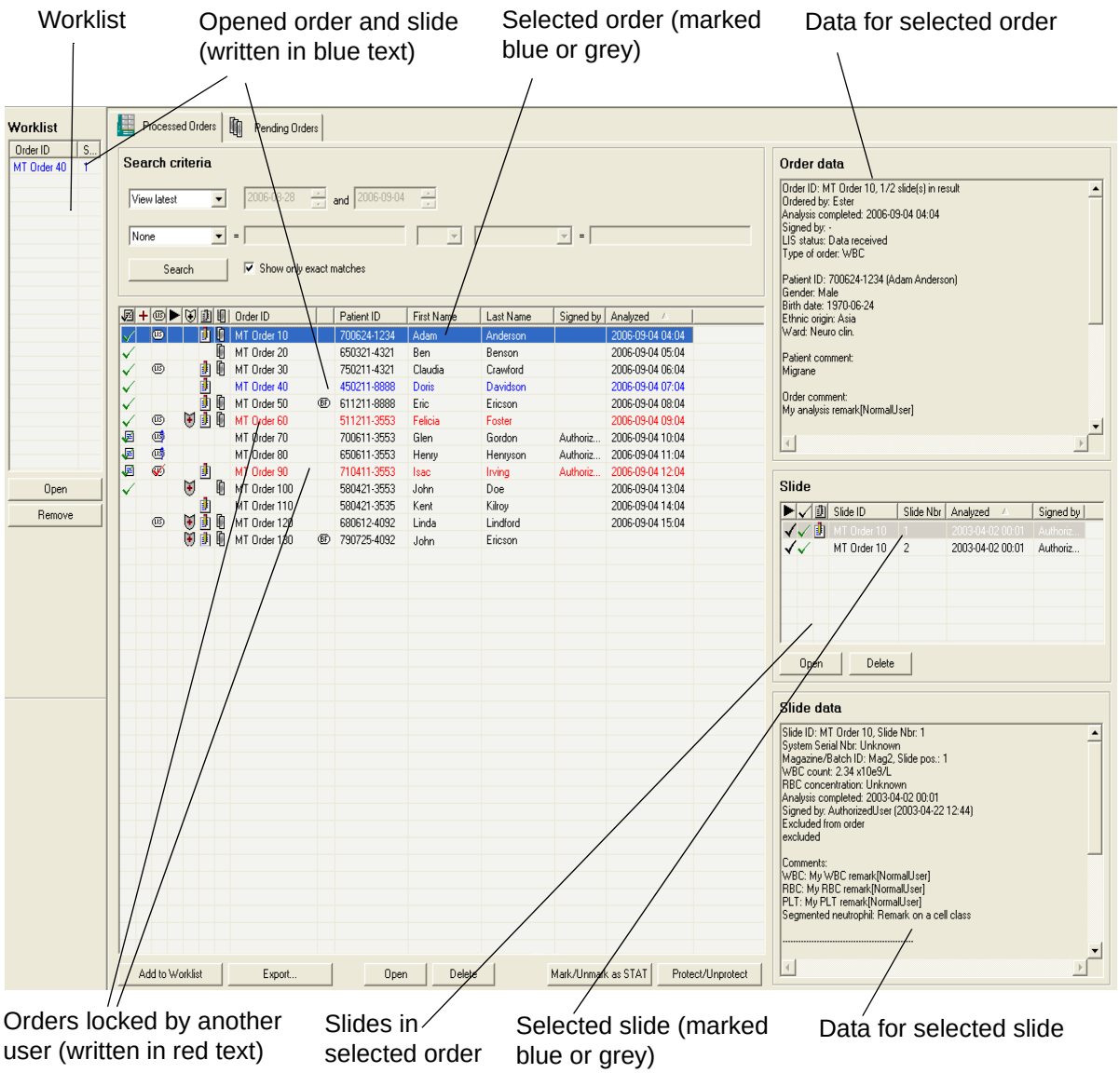
Processed and pending orders are stored in the database. You can switch between the two types, using the tabs *Processed Orders* and *Pending Orders*.

6.1 Database — Processed Orders

You can search for and open processed orders and slides stored in the system. Orders are displayed according to the *Search criteria*. Select an order to display more information in the *Order data* panel. All slides belonging to the order are shown in the *Slide* list. Select a slide to display more information in the *Slide data* panel.

(Cont'd)

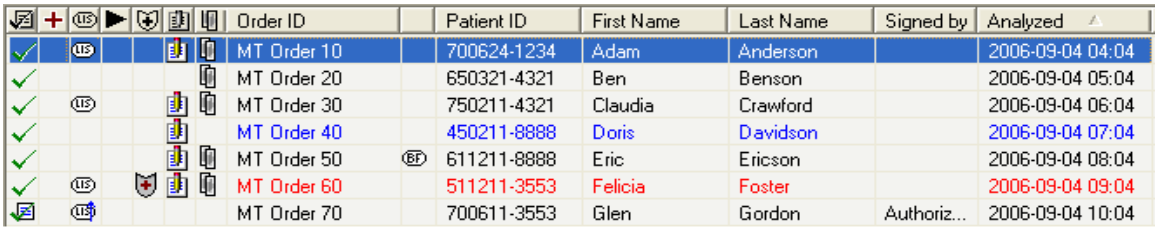
(Cont'd)


Worklist
Opened order and slide (written in blue text)
Selected order (marked blue or grey)
Data for selected order
Orders locked by another user (written in red text)
Slides in selected order
Selected slide (marked blue or grey)
Data for selected slide

An open order and slide is always written in blue text. An order/slide opened by another operator on a CellaVision® Remote Review/CellaVision DM is written in red text. In the *Order data* and *Slide data* panels, *Locked by* indicates who has opened the order/slide (the person logged on to Windows) and on which computer.

6.1.1 Order List

The *Order list* displays an overview of the orders. Click the column headers to sort the list. The date in column *Analyzed* corresponds to the processing date for the last slide in an order.



	Order ID		Patient ID	First Name	Last Name	Signed by	Analyzed
✓	MT Order 10		700624-1234	Adam	Anderson		2006-09-04 04:04
✓	MT Order 20		650321-4321	Ben	Benson		2006-09-04 05:04
✓	MT Order 30		750211-4321	Claudia	Crawford		2006-09-04 06:04
✓	MT Order 40		450211-8888	Doris	Davidson		2006-09-04 07:04
✓	MT Order 50	BF	611211-8888	Eric	Ericson		2006-09-04 08:04
✓	MT Order 60		511211-3553	Felicia	Foster		2006-09-04 09:04
✓	MT Order 70		700611-3553	Glen	Gordon	Authoriz...	2006-09-04 10:04

Order status

Empty field	No slide is signed.
✓	At least one slide is signed.
	Order is signed.
	Order is cancelled.

STAT mark +

Empty field	Not a STAT order.
+	Order is marked as a STAT order.

LIS status

Empty field	No data sent or received.
	Data received.
	Waiting to send result.
	Result is sent.
	Result is sent, send failure.
	Result is successfully sent.

(Cont'd)

(Cont'd)

Process status	▶
Empty field	All slides in the order have process status OK.
	Slide with process error in the order.
	Stopped slide in the order.
	Slide with process status in the order.

Archive status	
Empty field	Order is unprotected.
	Order is protected. Order and slides in this order cannot be deleted or archived.
	Order is archived.
	All images except *Region of interest* images have been deleted (only applicable for scan databases).

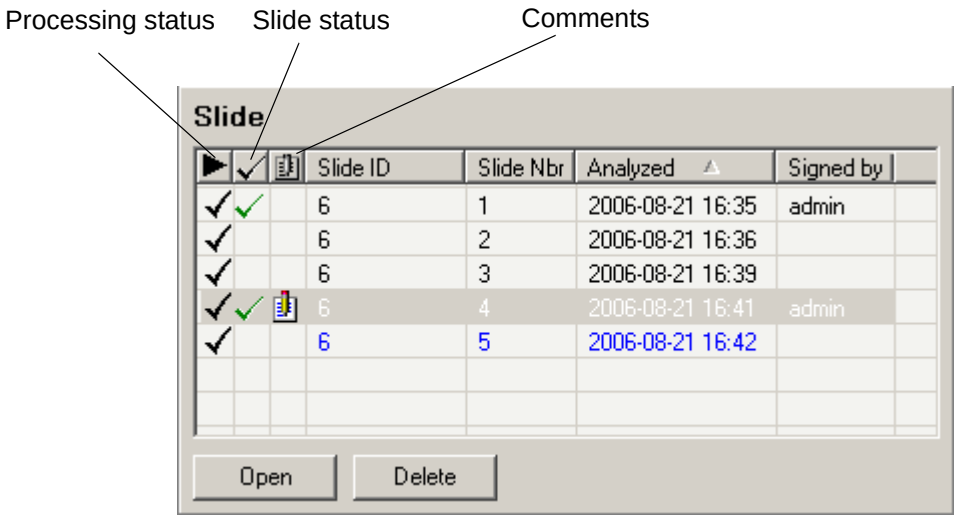
Comments	
Empty field	No comments.
	Comments exist.

Multi-slide status	
Empty field	One slide in order.
	More than one slide in order.
C	The order contains a cell counter confirmed result.

Order type	
Empty field	Peripheral blood order.
BF	Body fluid order

6.1.2 Slide List

Processing status



Process status ▶

✓	Slide processing OK.
STOP	Slide processing stopped. No result exists.
⚠	The required numbers of WBCs were not found, one of the ordered analyses failed, or the order was not found in the LIS, slide processed with default values.
✖	Processing error. No result exists.

Slide status ✓

Empty field	Not signed.
✓	Signed

Comments

Empty field	No comments.
	Comments exist.

6.1.3 Opening an Order/Slide

When you open an order you automatically open one slide belonging to it. In the same manner, opening a slide automatically opens the order it belongs to. The currently open order and slide are always shown in the toolbar.

Double-click on an order in the *Order list*, and the first slide of that order opens. You can also click Open in the *Order* panel. In the *Slide list* you can open specific slides in the same way.

You may close the order and the slide using a toolbar button.

Close Order and Slide

6.1.4 Protecting an Order

You may protect orders to prevent slides from being deleted or archived.

1. Select the order.
2. Click *Protect/Unprotect*.

You may select multiple orders using *Ctrl* or *Shift*.

6.1.5 Searching for an Order/Slide

You select the orders to be displayed using the *Search criteria*. Here, you may specify date intervals for desired orders. Use "View latest" as a shortcut for orders less than one week old. You may also add search strings for patient data, order data and comments.

6.1.6 Deleting an Order/Slide

A selected order/slide can be deleted by clicking *Delete*. Select multiple orders/slides using *Ctrl* or *Shift*. When all slides in an order have been deleted, the order is automatically deleted.

Note! *Signed slides cannot be deleted. However, deleting an order deletes all slides in the order, signed or not. Only Administrators can delete signed orders.*

6.1.7 Exporting Orders

You may export signed orders from the current database to another one.

An export database or a CellaVision® Competency Software database must be created before exporting can start. This can be done in the database settings tab (see 10.1.1 Creating a New Database).

a) Exporting to an export database

1. Select one or several orders.
2. Click *Export*.
3. Select a database in the list.
4. Check *Delete orders after export* to perform an export (the order will be copied if unchecked).
5. Click *Export*.

b) Exporting to a CellaVision Competency Software database

1. Select one or several orders.
2. Click *Export*.
3. Select a database in the list.
4. Click *Export*. Orders will not be deleted and patient data will not be copied.

Restrictions:

- Only signed orders can be exported.
- Orders imported to an export database will always have a "protected" flag preventing them from being autodeleted (if autodelete is enabled).
- Only peripheral blood orders can be exported to CellaVision Competency Software databases.
- Orders residing in a Scan database cannot be exported.

6.1.8 Copying Images to Disk

You can copy all images from selected orders to disk.

1. Select one or several orders.
2. On the right-click menu select *Copy images to disk…* and the *Copy images to disk* dialog appears.
3. Specify the destination path where you want the images to be saved.
4. Uncheck *WBC images* or *Overview images* (RBC/PLT images) to exclude this type of images.
5. Click *OK*.

Note! *The directory you specify in the destination path must exist.*

6.1.9 Printing Orders

You can print order data and data for all slides belonging to it. Select the *order/slide* and select *Print* in the *File* menu.

Note! *Order results exist only if the order contains at least one signed slide.*

6.1.10 The Worklist

The Worklist facilitates an automatic workflow (see Appendix D — Recommended Workflow). The Worklist contains shortcuts to slides. It is also active in *Verification* view to simplify opening of new slides. Double-click on a slide, or click *Open* to open it. Click *Remove* to remove slides from the Worklist. When a slide is signed or closed, it is automatically removed.

Note! *Show/hide the Worklist by pressing Ctrl+w.*

Adding Slides to the Worklist

Slides may be added to the Worklist both manually and automatically.

A) Manually

1. Select one or more orders.
2. Click *Add to worklist*. All slides belonging to the order(s) are added.

B) Automatically

1. Slides are added when the system finishes processing them. This option is set in *Analysis* in *Settings*.
2. When you open an order, all slides belonging to it are added.

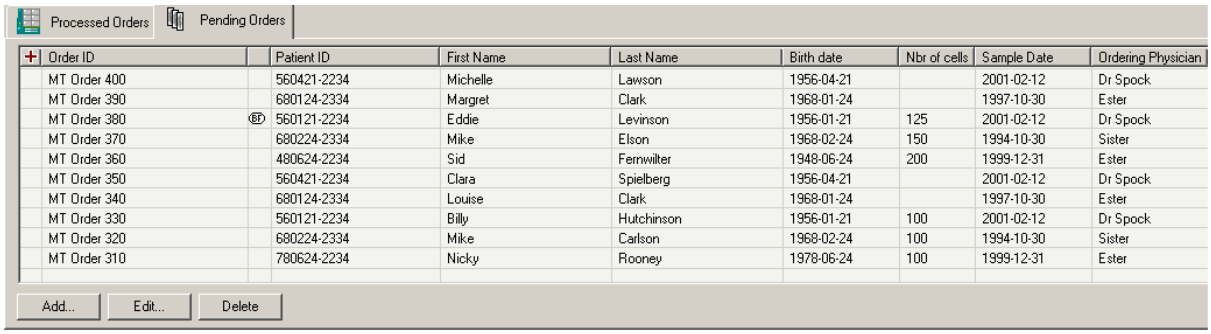
Note! *When the program is closed, the Worklist is emptied.*

Note! *BF slides are not automatically added to the worklist.*

6.2 Database — Pending Orders

This tab contains a list of all pending orders. A pending order is an order that has been manually added to the database, but not yet processed. This is useful if you do not have a connection to the LIS.

Note! *When an order has been processed it will be removed from the Pending Orders list and added to the Processed Orders list.*



Order ID		Patient ID	First Name	Last Name	Birth date	Nbr of cells	Sample Date	Ordering Physician
MT Order 400		560421-2234	Michelle	Lawson	1956-04-21		2001-02-12	Dr Spock
MT Order 390		680124-2334	Margret	Clark	1968-01-24		1997-10-30	Ester
MT Order 380	BF	560121-2234	Eddie	Levinson	1956-01-21	125	2001-02-12	Dr Spock
MT Order 370		680224-2334	Mike	Elson	1968-02-24	150	1994-10-30	Sister
MT Order 360		480624-2234	Sid	Fernwilter	1948-06-24	200	1999-12-31	Ester
MT Order 350		560421-2234	Clara	Spielberg	1956-04-21		2001-02-12	Dr Spock
MT Order 340		680124-2334	Louise	Clark	1968-01-24		1997-10-30	Ester
MT Order 330		560121-2234	Billy	Hutchinson	1956-01-21	100	2001-02-12	Dr Spock
MT Order 320		680224-2334	Mike	Carlson	1968-02-24	100	1994-10-30	Sister
MT Order 310		780624-2234	Nicky	Rooney	1978-06-24	100	1999-12-31	Ester

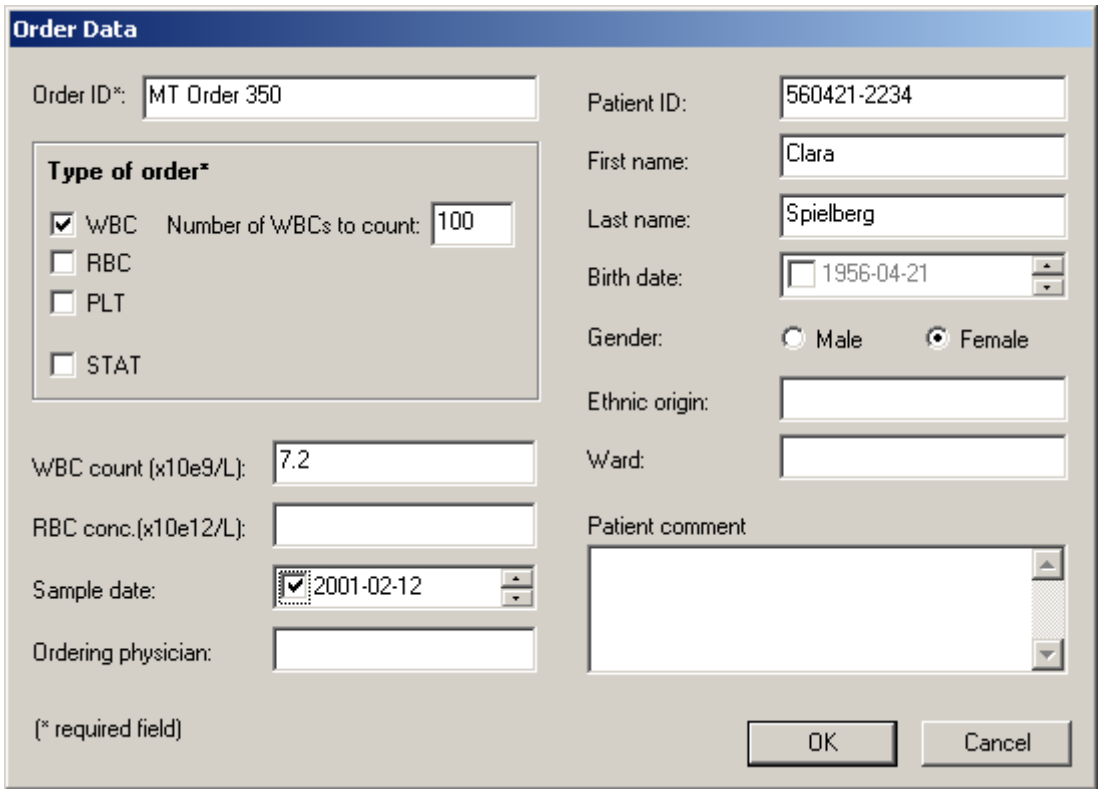
STAT mark	+
Empty field	Not a STAT order.
+	Order is marked as a STAT order.

Order type	
Empty field	Peripheral blood order.
BF	Body fluid order

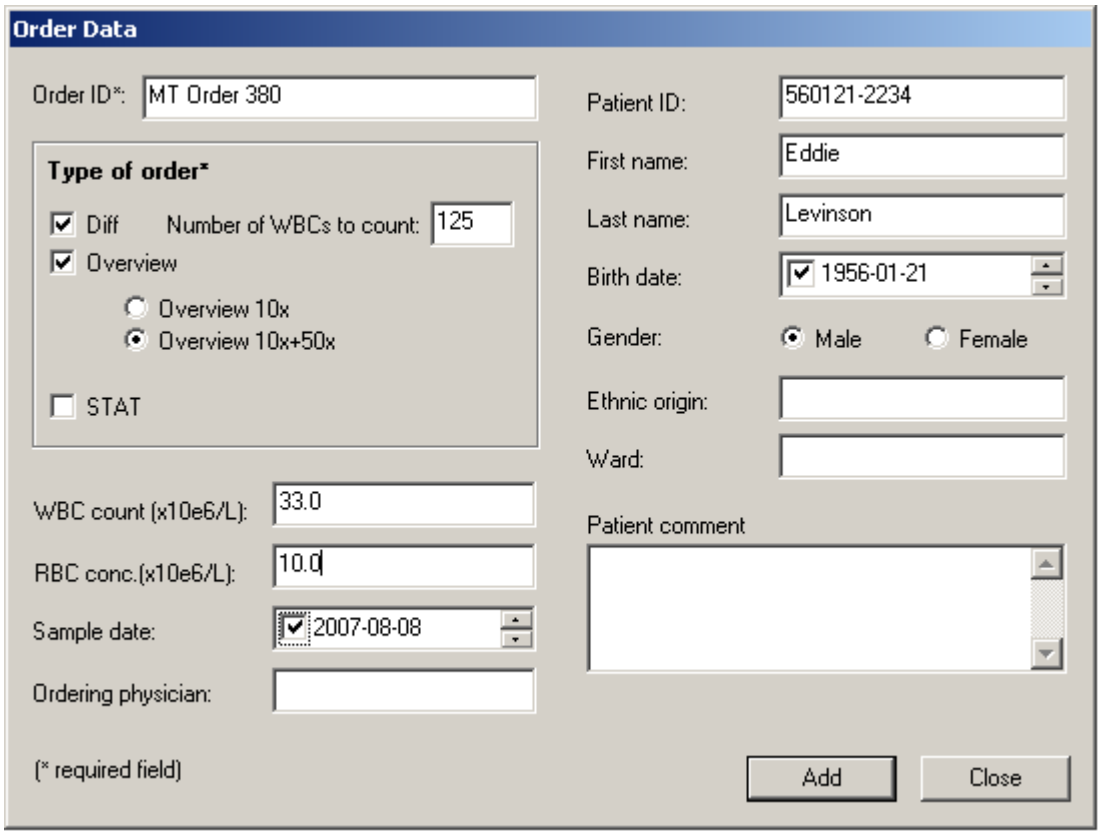
Click *Add* to add a new pending order.

Double-click on a pending order, or click *Edit*, to *view/edit* the Order Data.

6.2.1 Pending Orders Dialog for Peripheral Blood



6.2.2 Pending Orders Dialog for Body Fluid



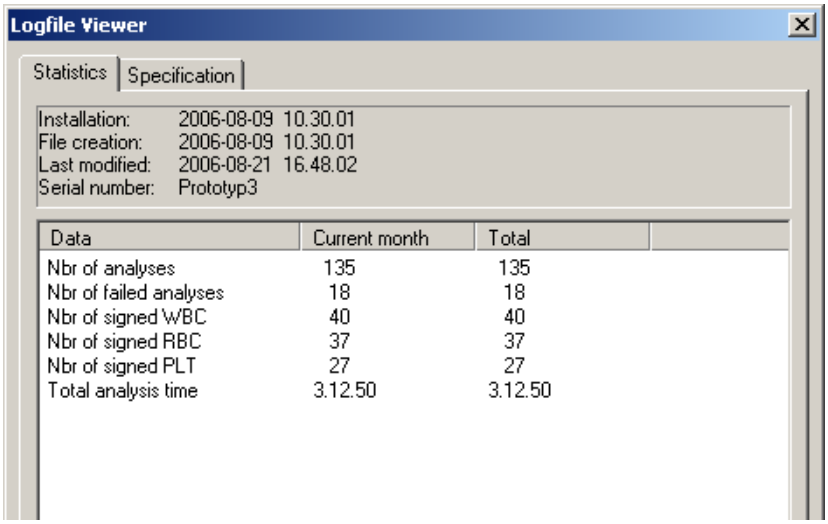
6.3 Archiving Data

Select *Tools/Archive* and the *Archiving Guide* will appear explaining the procedure. Make sure that a valid archiving media has been specified. This is done in the *Archiving* tab under *Settings* (see 10.11 Adjusting Archiving Settings).

6.4 Usage Log

The system continuously saves data of processed slides and stores it in a Usage log. To view this log select *Tools/ View Log*. The log consists of two pages, *Statistics* and *Specification.*

6.4.1 Statistics



The *Statistics* page contains dates and times of program installation and creation and modification of the Usage log. It also displays the number of successfully processed and failed slides, the number of signed analyses and the total processing time. The information can be selected for a specific month by entering *Year* and *Month* and clicking *Update*.

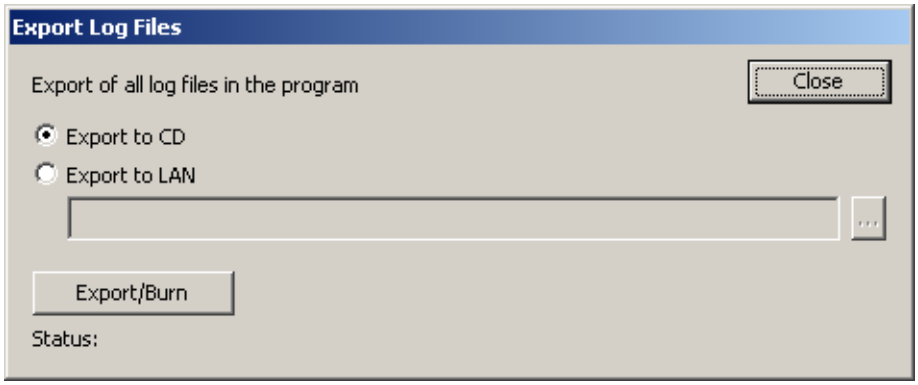
6.4.2 Specification

The *Specification* page is only accessible to Administrators. It contains a list of dates and times for events that have occurred in the system, e.g. start and completion of slide processing and hardware malfunctions. You may specify the month the same way as described above.

6.5 Export Log Files

It is possible to export all logging information from the system. If a system error occurs, the information is needed for trouble shooting. Select *Tools/ Export Log Files*. The log files can be burnt directly to a CD, or exported to the LAN (and then, for instance, attached to an e-mail).

Note! *CellaVision® DM must be idle during export. Otherwise, the export will not be complete.*



6.6 Backup and Recovery of the Database

It is important to backup the database quite often. If a hard disk crash occurs, the whole database will be lost. It will only be possible to recover the data up to the time when the last backup was made. Two types of backup procedures are described below: System backup and Online backup.

The main advantage of an online backup is that the database is backed up while the system can remain operational. A disadvantage is that there must be enough disk space available to copy the complete database. If the disk space is limited, a system backup can be preferable. For a system backup, the database server must be stopped.

It is possible to configure the database so that no data will be lost in case of a hard disk crash, but it is more complicated and requires at least two hard disks with separate disk controllers. For more information about this, contact your distributor.

6.6.1 System Backup

System backup is a simple file copy process performed from the operating system. The backup procedure must be performed by a Windows Administrator. Before the file copying can start the database server must be stopped. After the file copying, the database server must be restarted.

1. Start the program Mimer Administrator (*Start menu/All Programs/Mimer SQL Engine/Mimer Administrator*).
2. Right click on the database name in the *Local* tab, and select *Stop Server.* (Note that one column in the list specifies the home directory of the database).
3. Verify the database files (see 6.6.3 Verify Backup).
4. Use e.g. Windows Explorer to copy the files (*.dbf) in the database home directory to a backup location (normally tape or network drive).
5. Right-click on the database name again in the program Mimer Administrator and select *Start Server.*

6.6.2 Online Backup

An online backup is performed without stopping the database server. The backup procedure uses SQL system management statements and must be performed by a CellaVision DM software Administrator (but not necessarily a Windows Administrator).

First all data files (called databanks) in the database are backed up. Then the backup files are copied to a backup location (tape or network drive).

In the following example, the database is called mydatabase and it is backed up into a directory called c:\backupdir.

1. Start a command prompt (*Start menu/Run/cmd*).
2. At the prompt, type `bsql mydatabase` and press *Enter* to start the BSQL database tool.
3. Log on as Administrator (e.g. as 'admin').
4. At the prompt, type `START BACKUP`; and press *Enter* to start the backup procedure.
5. Type `CREATE BACKUP IN 'c:\backupdir\ciimg' FOR DATABANK ciimg`; and press *Enter.*
6. Type `CREATE BACKUP IN 'c:\backupdir\logdb' FOR DATABANK logdb`; and press *Enter.*

(Cont'd)

(Cont'd)

7. Type `CREATE BACKUP IN 'c:\backupdir\sqldb' FOR DATABANK sqldb`; and press *Enter*.
8. Type `CREATE BACKUP IN 'c:\backupdir\sysdb9' FOR DATABANK sysdb`; and press *Enter*.
9. Type `CREATE BACKUP IN 'c:\backupdir\transdb' FOR DATABANK transdb`; and press *Enter*.
10. Type `COMMIT BACKUP`; and press *Enter* to complete the backup procedure.
11. Type `EXIT`; and press *Enter* to exit the BSQL tool.
12. Type `exit` and press *Enter* to close the command prompt.
13. Verify the backup files (see 6.6.3 Verify Backup).
14. Use e.g. Windows Explorer to copy the files in the backup directory to a backup location (normally tape or network drive).

The name of the backup files should be the same as the original database files. (Note that the filename for the databank SYSDB may differ).

Note! *A more advanced, but easier to use, backup script is available through CellaVision or your local distributor.*

6.6.3 Verify Backup

The databank check (DBC) program should be run before archiving the backup copies of the databank files (e.g. copying them to tape or network) to verify the physical integrity of the databank files.

A report file is created each time the DBC program is run. In the following example, the report file is given the same name as the databank (but a different file extension).

1. Start a command prompt.
2. Type `dbc c:\backupdir\ciimg c:\backupdir\ciimg` and press *Enter*.
3. Type `dbc c:\backupdir\logdb c:\backupdir\logdb` and press *Enter*.
4. Type `dbc c:\backupdir\sqldb9 c:\backupdir\sqldb9` and press *Enter*.
5. Type `dbc c:\backupdir\sysdb c:\backupdir\sysdb` and press *Enter*.
6. Type `dbc c:\backupdir\transdb c:\backupdir\transdb` and press *Enter*.
7. Type `exit` and press *Enter* to close the command prompt.

If a databank file is corrupt in some way, 'Errors are logged' is shown. The errors are logged in the report file. Normally the message 'No errors found' is shown.

If the DBC program reports that a databank file is corrupt, the database backup procedure must be re-run.

6.6.4 Recovery

If the hard disk crashes or the database files become corrupt because of some other reason, an old backup can be used. Always use the most recent backup.

Note! *All data stored in the database since the last database backup will be lost in case of a hard disk crash. It is recommended to frequently backup the database.*

To restore a database from a backup, do as follows:

1. Stop the database server using Mimer Administrator if necessary. A program called Mimer Controller can also be used to stop (and start) the database server.
2. Copy all database files (*.dbf) from the backup location (c:\backupdir in the examples above) to the home directory (can be viewed in Mimer Administrator).
3. Restart the database server.

7 Digital Slides

With CellaVision® DM96 it is possible to create digital slides.

Important

The digitalized image generated provides a general overview of the prepared sample within the intended use of the CellaVision DM96 applications. All other use is for research use only and not for use in diagnostic procedures.

7.1 Scanning a Slide

Make sure that a Scan Database is available on your CellaVision DM. To create a Scan Database, see 10.1.1 Creating a New Database.

Log on to a Scan Database, see 2.1 Starting the System.

To customize your system, such as scan area and magnification, see 7.4 Customizing the System.

7.1.1 Slide and Magazine Requirements

Requirements for the slides used when scanning:

- Glass
- Size in mm: 75.0-76.0 x 25.0-26.0 x 0.9-1.2
- Ground edges
- Clipped or round corners
- Barcode labeled
- Frosted end

Note! *When using cover slips, make sure the scanning area is within the cover slip area.*

Note! *Coverslipped slides are supported as long as the total thickness of the slide is within the requirements.*

Note! *CellaVision DM96 analyzers with a serial number higher than 31216 or systems that have been upgraded with the Stage Upgrade Kit (CellaVision Part number XU-10043) support slides with the following dimensions (mm): 75.0-76.0 x 25.0-26.3 x 0.9-1.2*

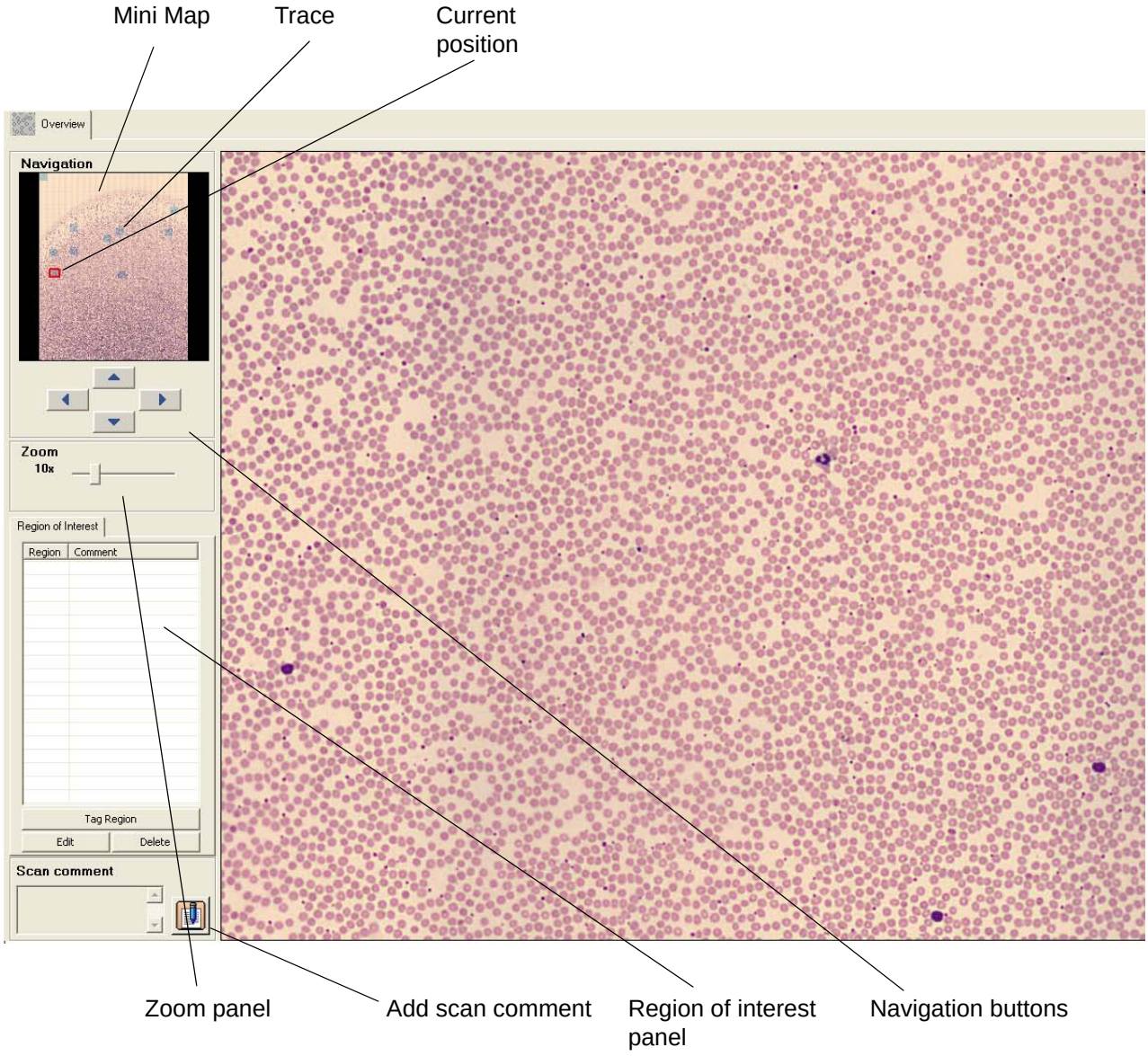
Note! *Any type of CellaVision magazines can be used for a scan analysis.*

7.2 Scan Overview Image

Opening a scanned slide leads directly to the *Scan Verification View*. To open a slide, see 6.1.3 Opening an Order/Slide.

7.2.1 Overview

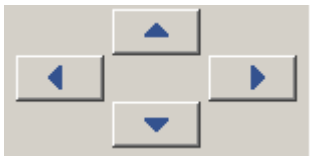
The *Mini Map* shown in the *Overview* displays the entire sample area. To enlarge a specific area of the sample, click in the *Mini Map*. The magnified area will be displayed in the large image on the screen. On the *Mini Map*, a red rectangle marks the area requested for enlargement. A blue trace marks an already viewed area.



The enlarged area can either have a 10x zoom or a combined 10x and 50x zoom. Using both zoom levels will increase the processing time.

7.2.2 Navigating

Move efficiently in the *Mini Map* by using the keyboard arrows or the *Navigation Buttons*.



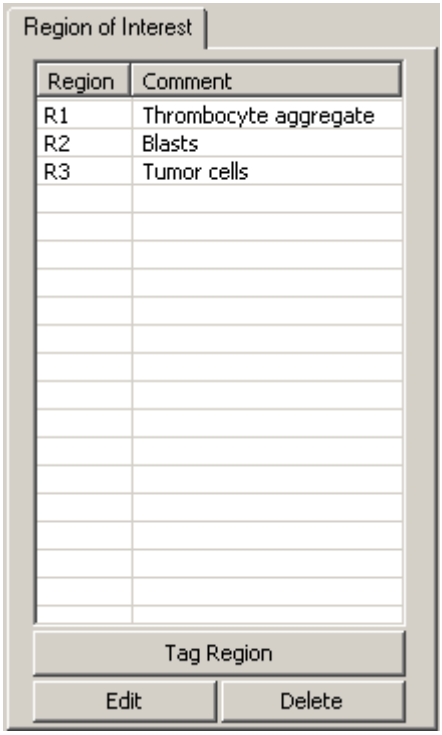
The image shown in the right part of the screen is an enlargement of the area inside the red rectangle shown in the *Mini map*. Click on the *Mini map* to enlarge another part of the sample. A blue trace in the *Mini map* indicates which parts of the overview image that have been viewed by the operator.

Hold left mouse button down and scroll in any direction using the mouse.

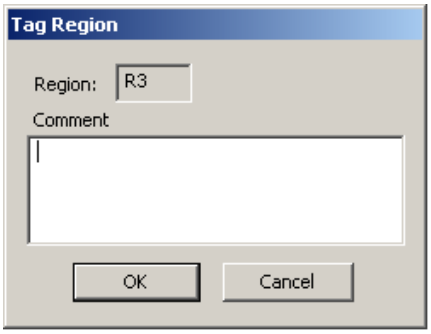
Switch between 10x and 50x zoom levels by right-clicking in the enlarged image. Adjust the zoom level by dragging the sliders in the *Zoom* panel.

7.2.3 Tagging Regions of Interest

To save an enlarged area as a region of interest for later reference, click *Tag region*.



Identify your region of interest by adding a comment.



7.2.4 Copying Regions of Interest to Disk

You can copy a region of interest to disk.

1. Select a tagged region of interest in the list.
2. Right-click and select *Copy the image to disk…*.
3. Specify the destination path where you want the image to be saved.
4. Click *OK*.

7.2.5 Adding Comments

To add a comment to the Overview, click *Scan comment*.

Scan comment

7.2.6 Order Data

To view information about the order, e.g. scanned area and comments, click *Order Data* in the toolbar. The *Order Data* dialog can also be accessed by right-clicking on an order in the database view.

To edit order data, click *Order Data* in the toolbar.

7.3 Database View

To view processed and pending orders, click *Database View.*

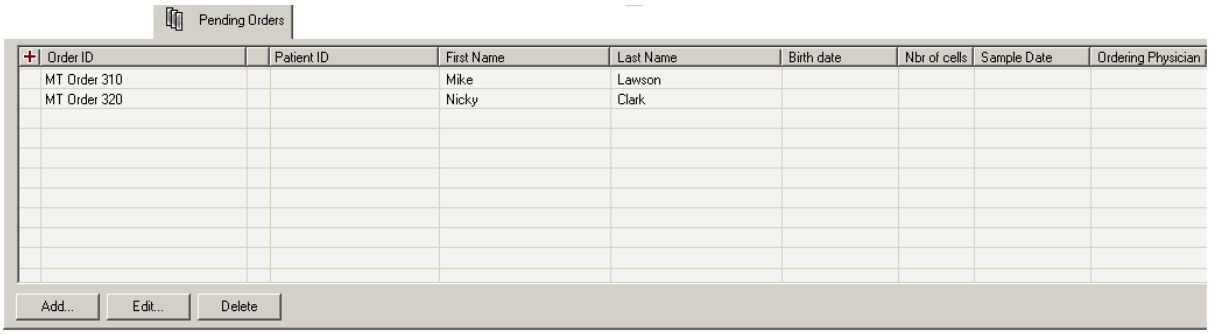
Click *Database View* in the toolbar.

7.3.1 Processed Orders

Scanned slides are automatically signed. For more details about Processed orders, see 6.1 Database — Processed Orders.

7.3.2 Pending Orders

A pending order has manually been added to the database and has not yet been processed. Pending Orders are useful when defining scan area for individual slides.



To add an order, click *Add*.

To view or edit order data, double-click on an order or click *Edit*.

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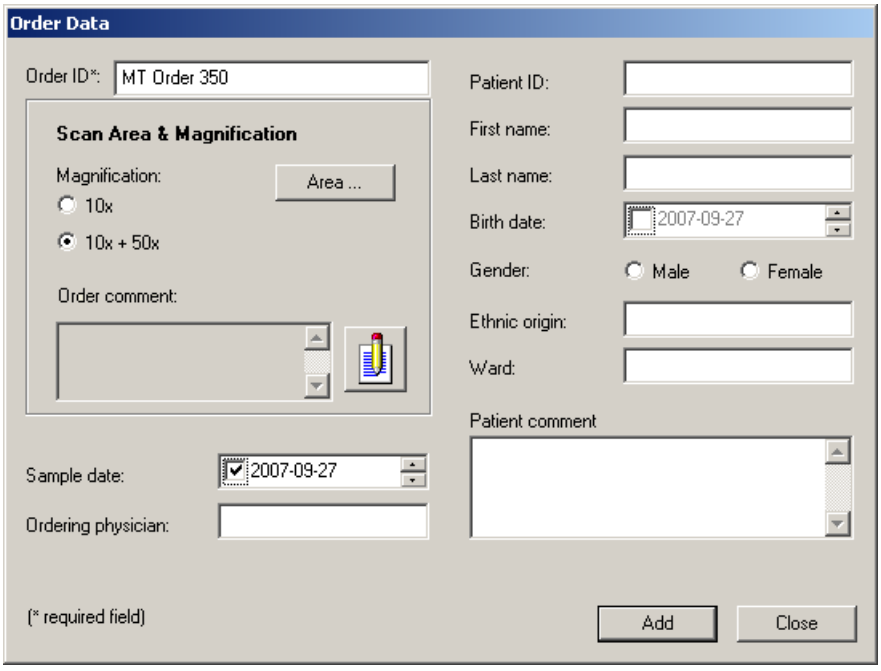
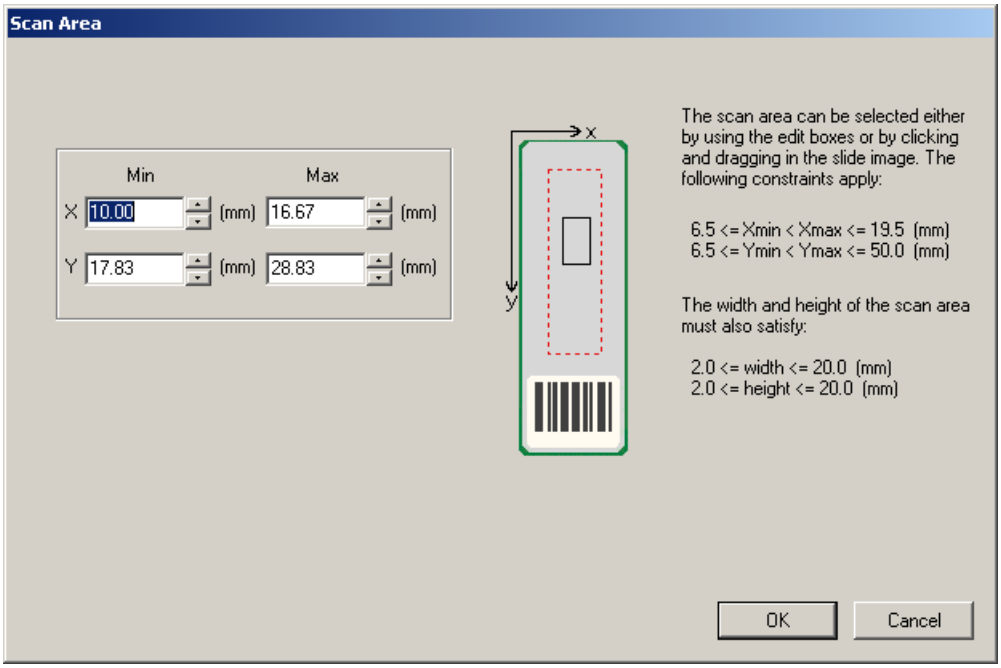


To define scan area for the slide, click *Area*. Define the area that you want to scan on this particular slide.



Note! *If no scan area is defined, the default scan area setting will be used.*

7.4 Customizing the System

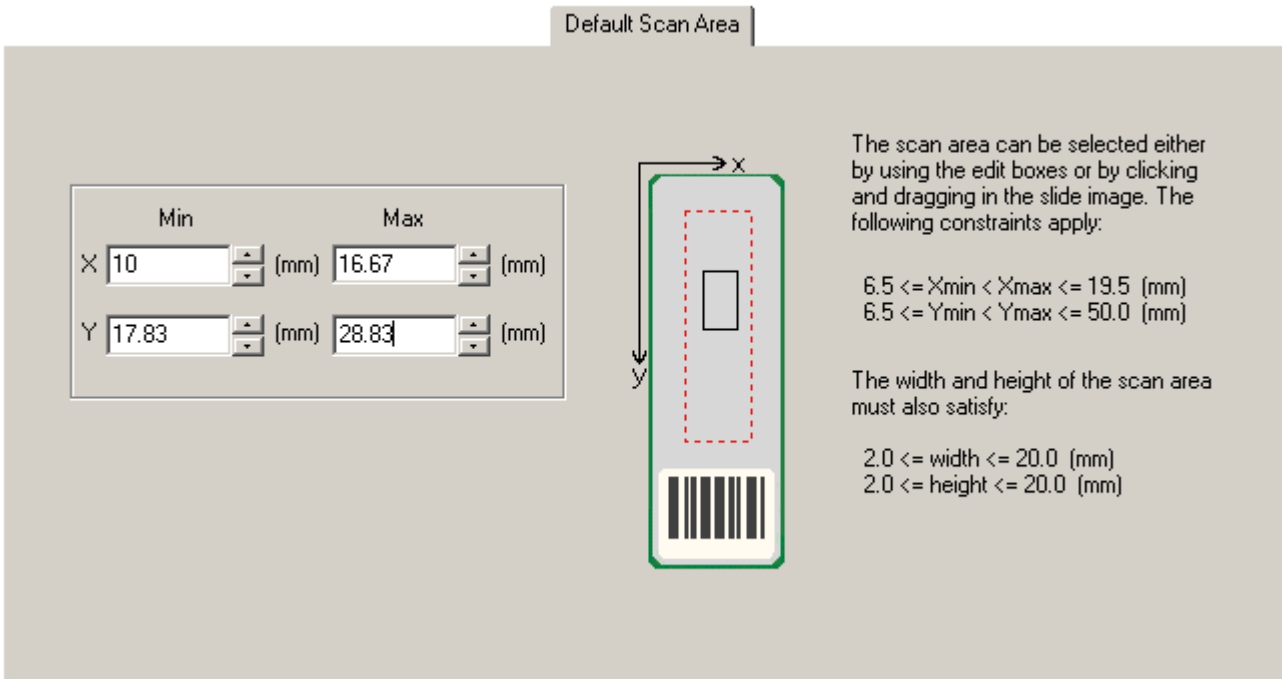
To customize the system, go to the *Tools* menu and select *Settings*.

7.4.1 Adjusting Database, Users and Language

To adjust the settings for database, users and language, see 10.1 Adjusting Database Settings, 10.2 Adjusting Users Settings and 10.12 Adjusting Language Settings.

7.4.2 Adjusting Default Scan Area

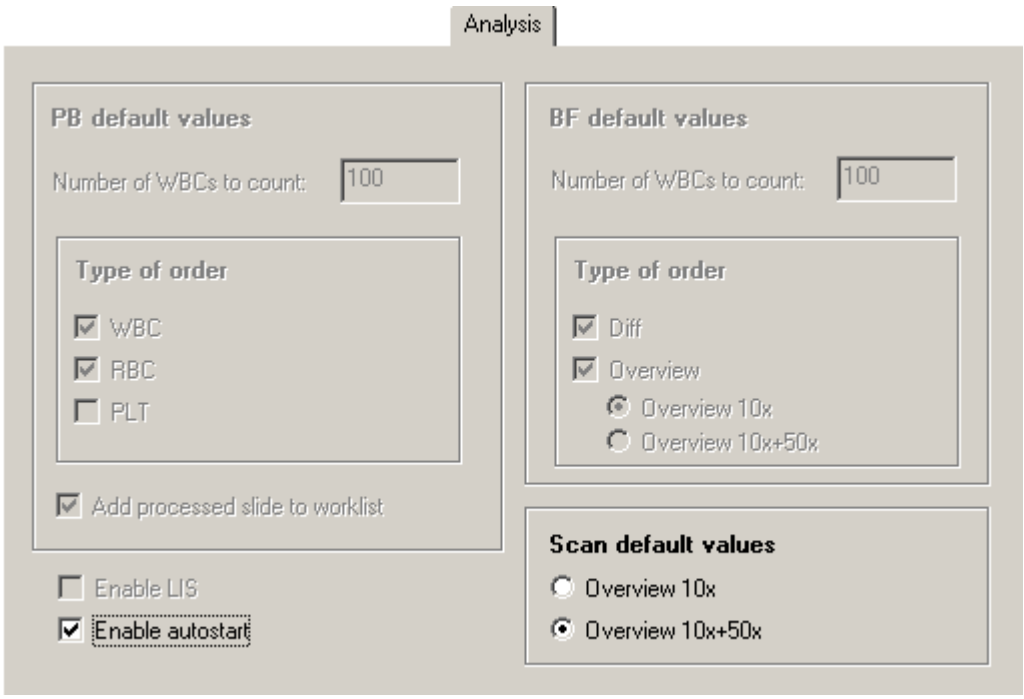
To adjust the default scan area, go to *Tools/Settings/Default Scan Area*.



To adjust the scan area settings for individual slides, click *Database View* and select *Pending Orders*. See 7.3.2 Pending Orders.

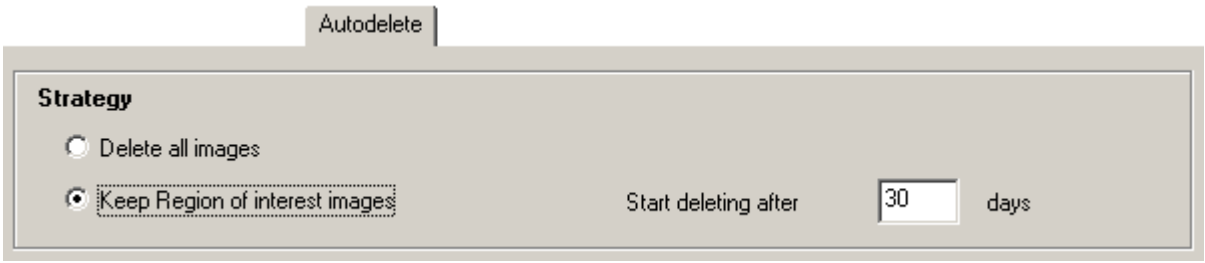
7.4.3 Adjusting Analysis

To adjust the default analysis settings, 10x or 10x and 50x magnification, go to *Tools/Settings/Analysis*.



To adjust the analysis settings for individual slides, click *Database View* and choose *Pending Orders*. See 7.3.2 Pending Orders.

7.4.4 Adjusting Autodelete



It is not possible to archive the orders. All orders will be autodeleted after a specified number of days.

Autodelete Strategy

The autodelete strategy depends on your throughput and the need for saving images for future use. The autodelete settings are database specific, enabling each database to have its own autodelete strategy.

Delete all images:

All orders and images are permanently deleted when the time has expired.

Keep Region of interest images:

The orders are not deleted, but all images except the *Region of interest* and *Mini map* images are deleted when the time has expired.

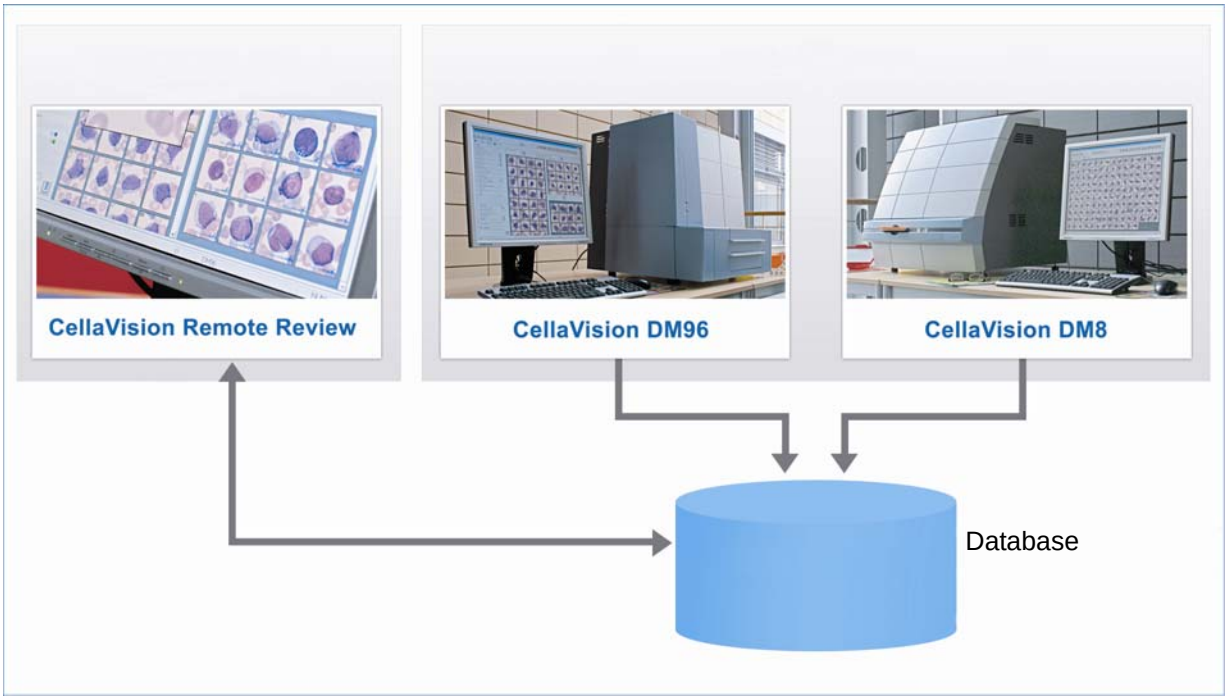
8 System Information

Information about your system is available from *Help/System Information*. The information presented depends on your system and installed software. Some of the following information is present in the dialog.

- Serial number of your system.
- The type of Artificial Neural Network (ANN) used.
- The computer name.
- The computer's IP address.
- Free disk space.
- Free physical and virtual memory.
- Total physical and virtual memory.
- Licensed software.
- License expiry date.

9 CellaVision® Remote Review — Multiple Users

A CellaVision Remote Review has network access to a database containing data from slides processed by CellaVision DM.



The operating procedures in *Database View*, *Verification View* and *Report View* are the same for CellaVision Remote Review as CellaVision DM. It is not possible to process slides or archive data using CellaVision Remote Review.

9.1 Working with Orders/Slides

When opening an order/slide with CellaVision DM or a CellaVision Remote Review the order and the slide will be locked for other operators. In all other CellaVision Remote Review and CellaVision DMs connected to the database this is indicated with red color in *Order list* and *Slide list* in the *Database View* (see 6.1 Database — Processed Orders). A locked order/slide can be opened but not modified, i.e. no changes can be done in *Verification View* and *Report View*. In the *Order data* and *Slide data* panels, *Locked by* indicates who has opened the order/slide (the person logged on to Windows) and on which computer.

10 Customizing the System

Settings are stored in either the system (or CellaVision® Remote Review) or the database.

A setting that is stored in the system applies to that system only. Other systems connected to the same database as the system may have other values of the setting.

A setting that is stored in the database applies to all systems connected to the same database. If you change the setting, it will be changed for all systems connected to the database.

The following settings are stored in the database:

- Restricted user search options
- User settings
- Analysis default values
- Enable LIS
- Add processed slide to worklist
- WBC reclassification settings
- RBC precharacterization settings
- PLT settings
- Active report template
- Report template contents
- Default settings for sign dialogs
- Standard comments
- Custom reference cells
- Autodelete/Archiving settings

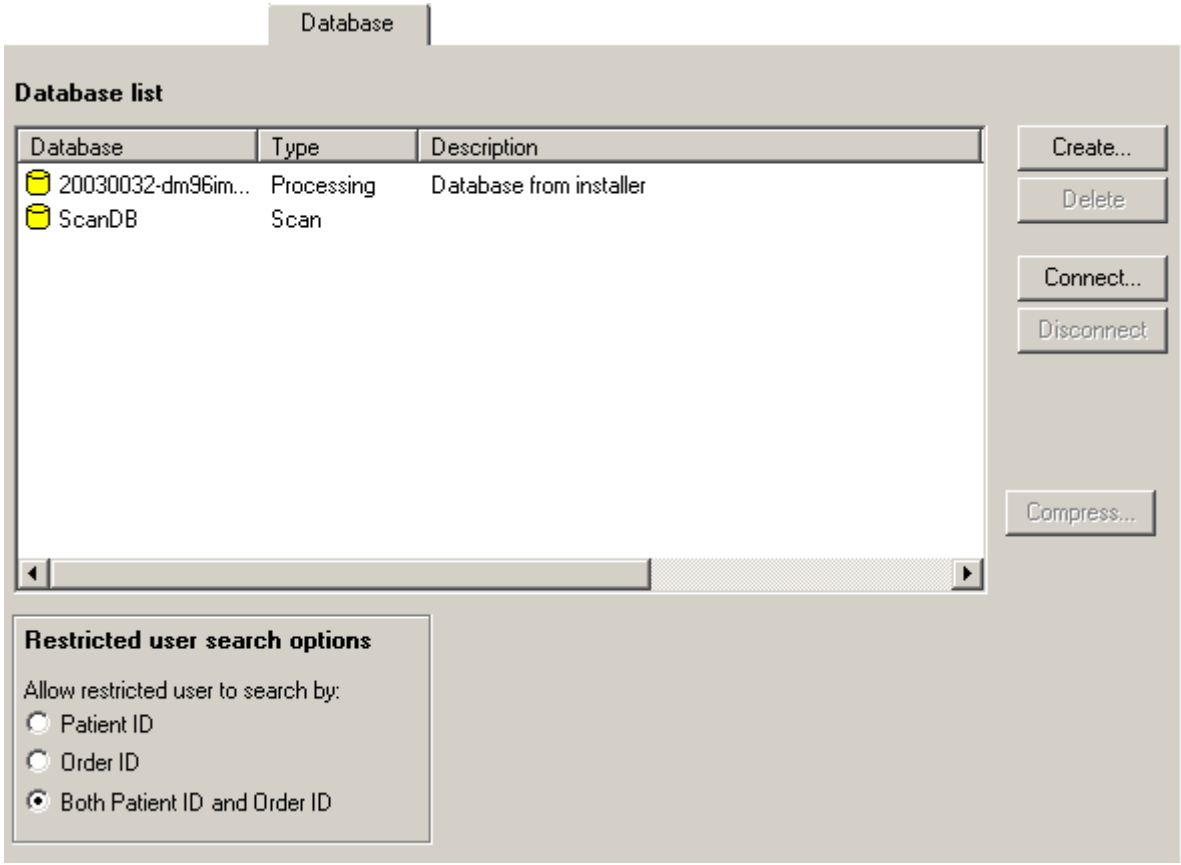
The following settings are stored in the system:

- Enable autostart
- Email settings
- Language
- Body fluid analysis area

Select *Tools*, followed by *Settings* and the appropriate tab to customize the system. Different users are allowed to edit different settings (see Appendix E — User Authorization Levels).

10.1 Adjusting Database Settings

Here you create new databases and new database connections. In the *Log On* dialog you select which database to use. It is also possible to compress an existing local database.

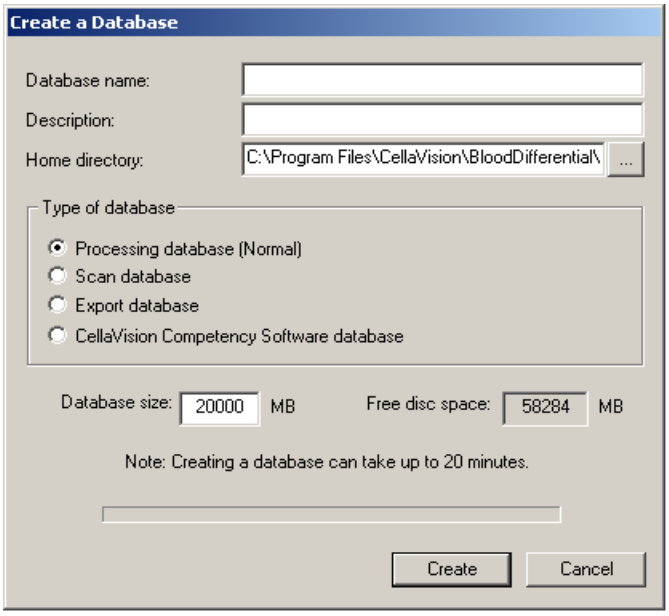


10.1.1 Creating a New Database

1. Click *Create*. A dialog appears, where you may enter *Database name*, *Description*, *Home directory* and *Database size*.
2. Select one of the following types of database:

- Processing database, a database for processing slides.
- Export database, a database that is used when you want to export orders from another database. This type cannot be used for processing slides.
- CellaVision® Competency Software database, a database for use with CellaVision Competency Software. A CellaVision Competency Software database cannot be used for processing slides.
- Scan database, a database for scanned slides.

3. Click *Create*. A new folder with the chosen Database name will be created in the specified *Home directory*.



Creating a database requires that there is sufficient free disk space. A processing database requires 20 GB, a scan database requires 20 GB, an export database requires 1 GB and a CellaVision Competency Software database requires 100 MB.

Note! *Having many databases affects system performance negatively.*

Note! *A database can be created only on your local computer.*

10.1.2 Deleting a Database

1. Select the database in the list.
2. Click *Delete*.

10.1.3 Creating a New Database Connection

1. Click *Connect*. A dialog appears where you may enter Database name, Description and Remote computer.
2. Click *OK*. A new connection will be shown in the list.

Note! *On the remote computer, select Help/System Information to find out the name of the computer.*

10.1.4 Deleting a Database Connection

1. Select the connection in the list.
2. Click *Disconnect*.

10.1.5 Compressing a Database

1. Select the database in the list.
2. Click *Compress*. A dialog appears.
3. Click *Compress database*.
4. Click *Close*.

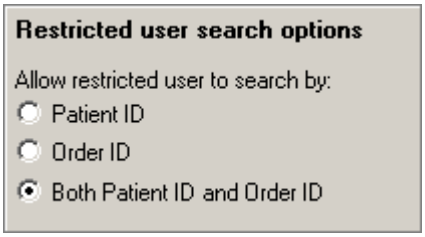
A compressed database will occupy less space on the hard disk. The performance might also be improved.

Note! *It can take a long time to compress a database. If the database is >10 GB in size it can take some hours. The process requires free disk space twice the size of the database to be compressed.*

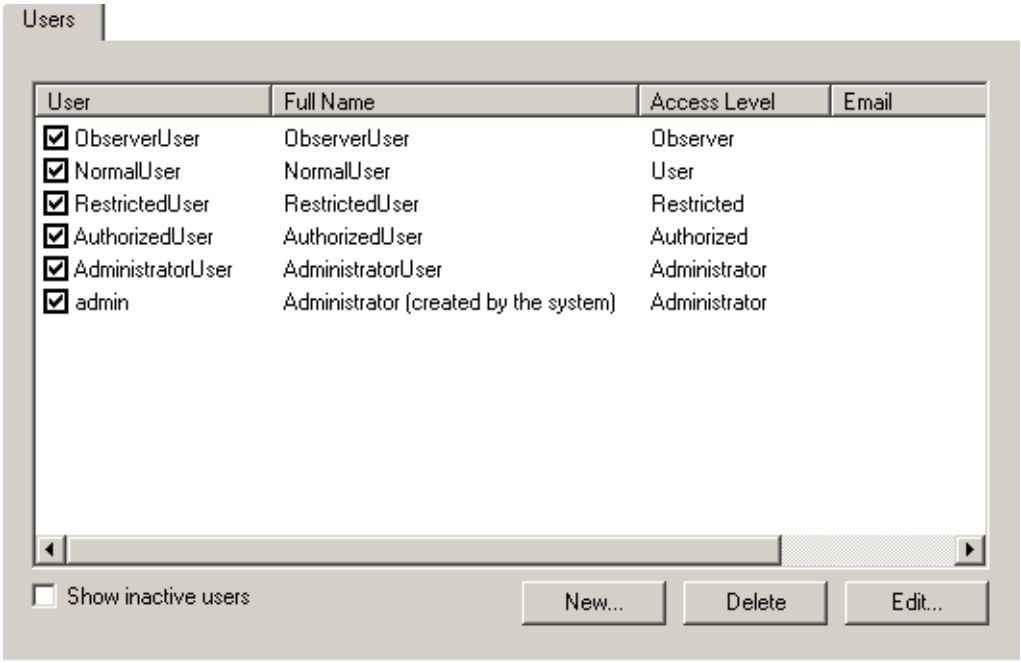
Note! *During compression, no client may be connected to the database! This means that you cannot compress the database you are currently logged on to.*

10.1.6 Setting User Restrictions

Here you set the available database search criteria for the Restricted user. Select the desired *Restricted user search options*.



10.2 Adjusting Users Settings



Show inactive users: Activate this checkbox if inactive users shall be shown in the list.
New: Add a new user (see dialog below).
Edit: Edit user information (see dialog below).
Delete: Delete selected users.

(Cont'd)

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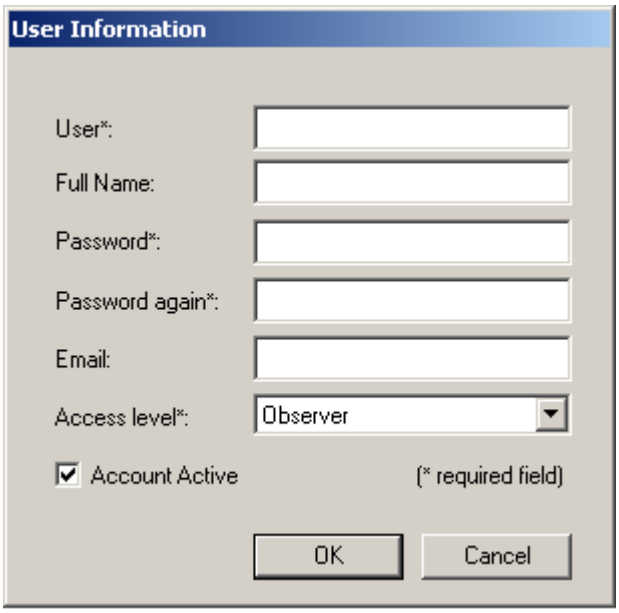
There are 5 levels of user authorization:

Observer: Only allowed to view images and results.
User: Can reclassify and recharacterize WBC, RBC and PLT, but not sign slides.
Authorized: Same as User, but can sign slides and orders.
Restricted: Same as Authorized, but with restricted database access.
Administrator: Full access to the system.

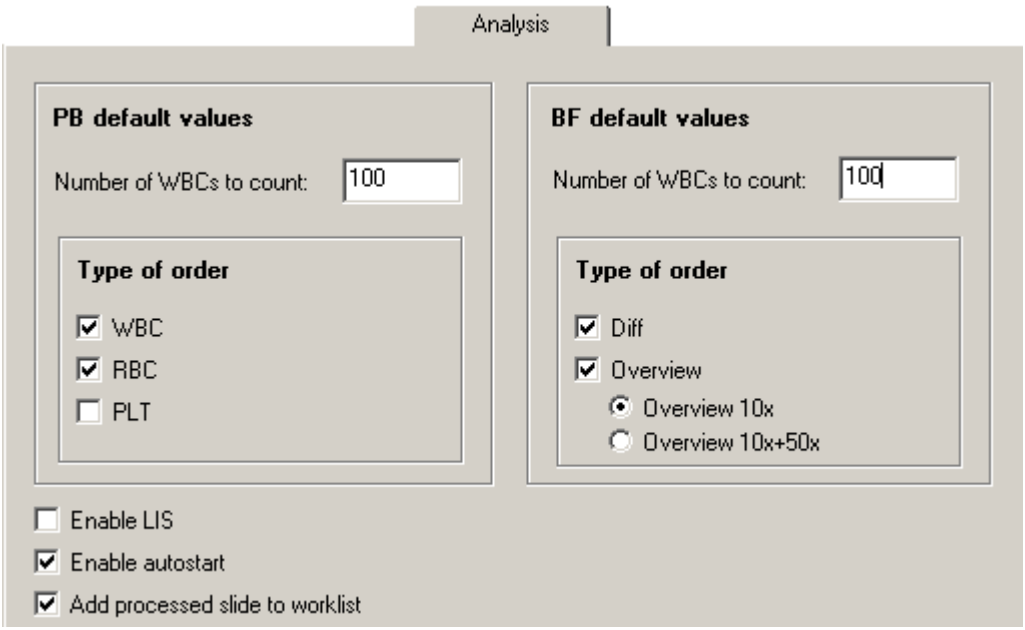
The authorization level determines the different functions and features the operator can access (see Appendix E — User Authorization Levels).



User: Login name. The checkbox Account Active indicates if the account is active.
Full Name: Full name of the operator.
Access Level: Level of user authorization.
E-mail: The operator's e-mail address.

Note! *When you create a new user the username must be unique and start with a letter (a-z or A-Z). The following words are reserved: SYSTEM, SYSADM, SYS, SELECT, TABLE, USER,UPDATE, IF, IS.*

10.3 Adjusting Analysis Settings



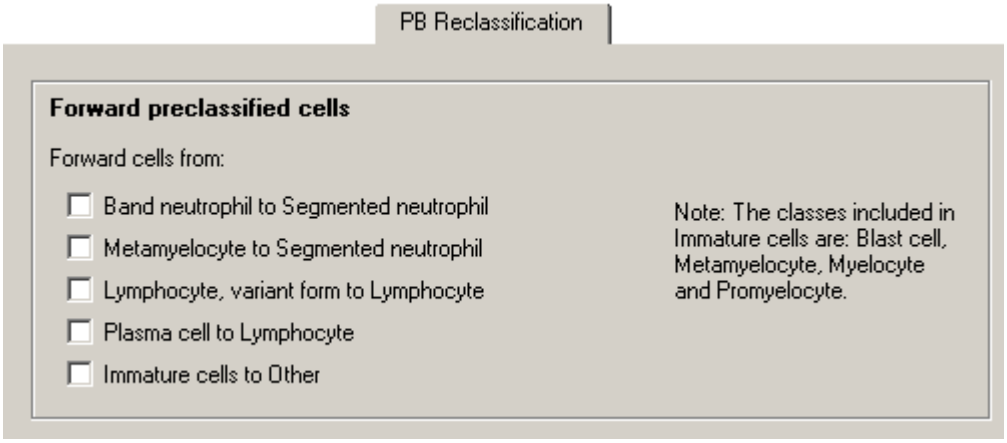
Default values
These values are used if the order to analyze is not found in the database or in the LIS. Type of order is the analysis to perform.

Enable LIS
Activate this checkbox and restart the program if the LIS will be used.

Add processed slide to worklist
If this checkbox is activated, processed slides will automatically be added to the Worklist.

Note! *BF slides are not automatically added to the worklist.*

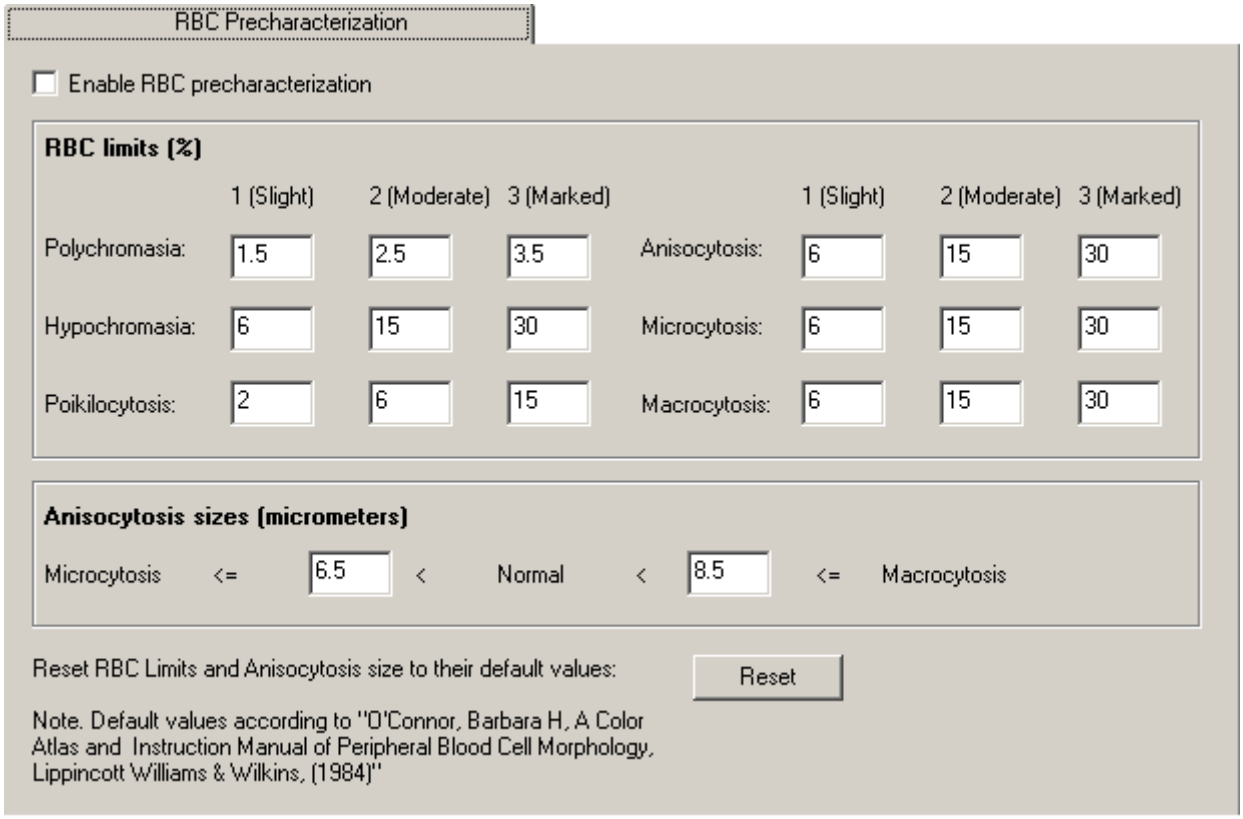
10.4 Adjusting Reclassification Settings


PB Reclassification
Forward preclassified cells
Forward cells from:
Band neutrophil to Segmented neutrophil
Metamyelocyte to Segmented neutrophil
Lymphocyte, variant form to Lymphocyte
Plasma cell to Lymphocyte
Immature cells to Other
Note: The classes included in Immature cells are: Blast cell, Metamyelocyte, Myelocyte and Promyelocyte.

Forward preclassified cells: Select your forwarding criteria using the checkboxes.

10.5 Adjusting RBC Precharacterization Settings

Here you adjust the percentage limits for the different levels of the morphology characteristics. It is also possible to disable the RBC precharacterization.



Enable RBC precharacterization: Deactivate this checkbox if RBC precharacterization shall not be performed. Manual RBC characterization will still be possible.

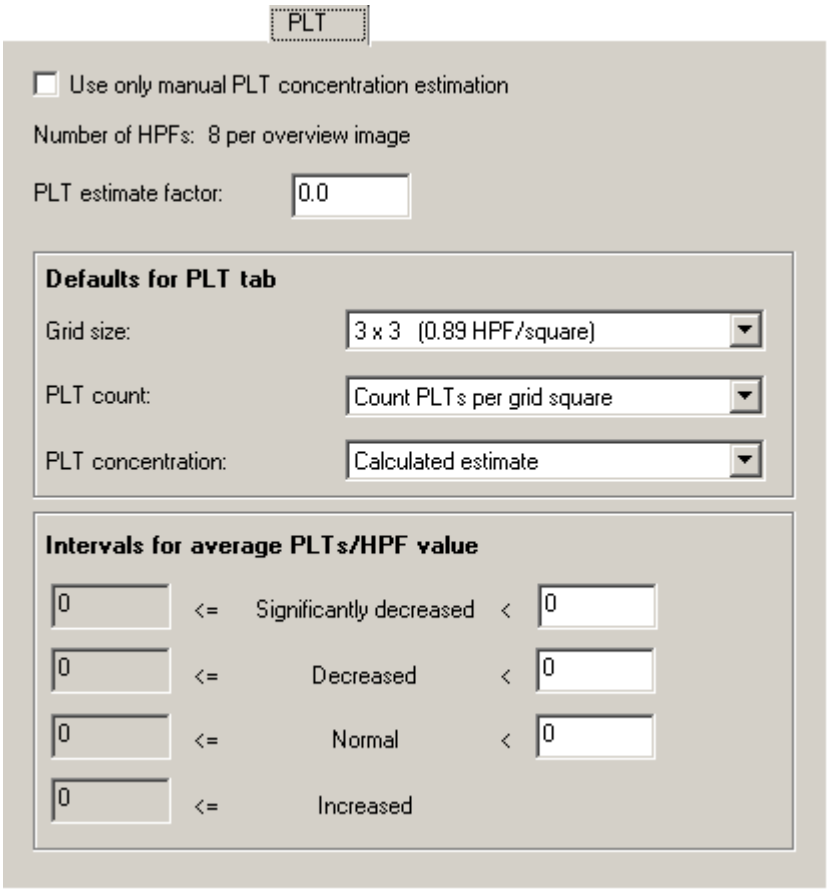
RBC limits: The percentage limits used for RBC precharacterization. The default values are set according to O'Connor, Barbara H, A Color Atlas and Instruction Manual of Peripheral Blood Cell Morphology, Lippincott Williams & Wilkins, (1984).

Anisocytosis sizes: Set size limits for precharacterization of Anisocytosis.

Reset: Resets all RBC limits and Anisocytosis sizes to their default values.

10.6 Adjusting PLT Settings

In the *PLT* tab you set the *PLT estimate factor* and the limits for the PLT concentration levels. You also set the default settings for the *grid size*, *PLT count* and *PLT concentration result*. It is also possible to enable the option to use manual PLT concentration estimation.



Use only manual PLT concentration estimation: When this checkbox is activated PLT estimation is done by estimating the concentration level to *Significantly decreased*, *Decreased*, *Normal* or *Increased*. No values for the PLT count can be entered and no calculation can be performed. This setting takes effect the very first time a slide is opened and can then not be changed for the order.

PLT estimate factor: See Appendix F — Determining the Platelet Estimate Factor for how to determine the PLT estimate factor.

Important

You have to determine your own PLT estimate factor. By default, it is set to "0".

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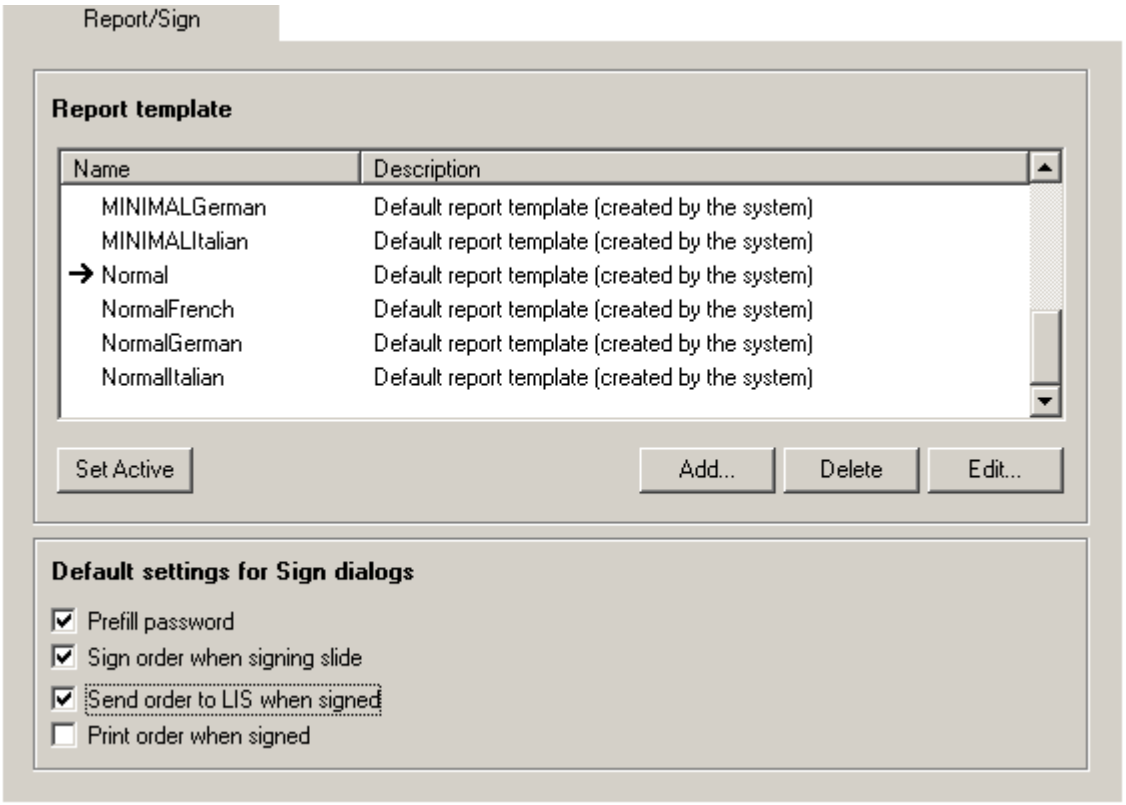
Defaults for PLT tab: Sets the default values for Grid size, PLT count and PLT concentration.

Intervals for average PLTs/HPF value: These intervals are used to calculate the PLT result Calculated level.

10.7 Adjusting Report/Sign Settings

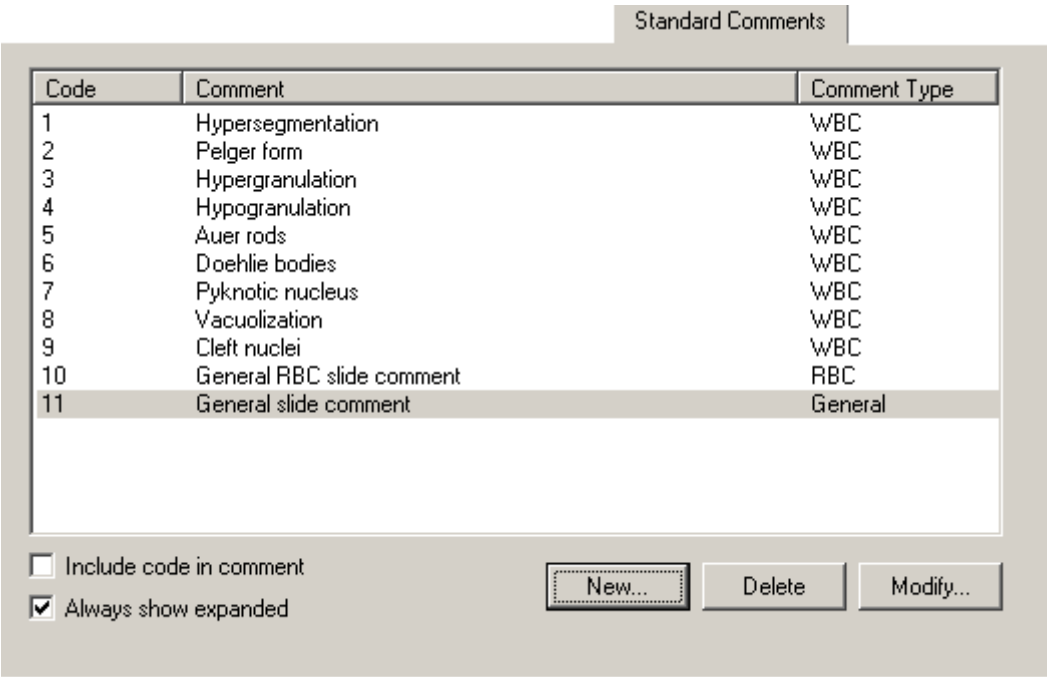
In the *Report/Sign* tab you set the template to use in printed reports and the default settings for the signing dialogs.



Report: All available templates are displayed in the list. The currently used template is indicated with an arrow. To change which template to use, select a template in the list and click *Set Active*.

Default settings for Sign dialogs: Here you set the default values for the *Sign Slide* and *Sign Order* dialogs.

10.8 Adjusting Standard Comments Settings



Include code in comment: If activated, the code is written together with the standard comment.

Always show expanded: If activated, the standard comments are visible by default when the comment dialog is opened.

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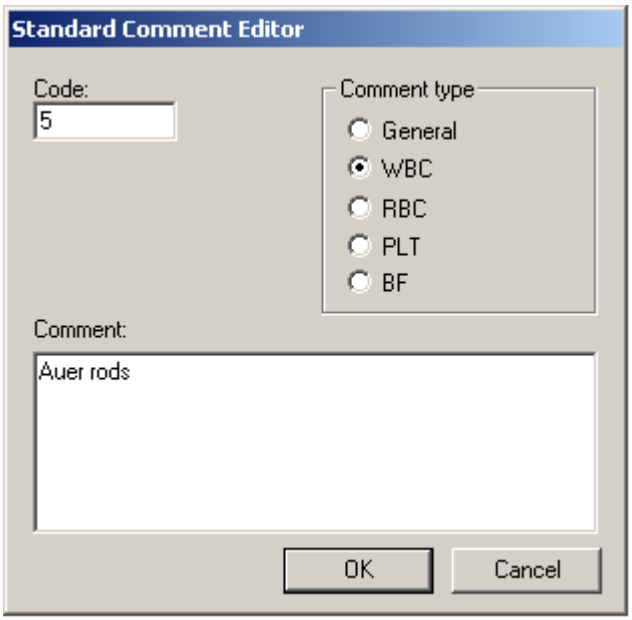
Adding a New Standard Comment

1. Click *New*.
2. The *Standard Comments Editor* appears.



3. *Enter Code, Comment type* and *Comment*. Standard comments of type WBC, RBC, PLT or BF will only be available in the respective tab. General comments are always accessible.
4. Click *OK*.

Deleting a Standard Comment

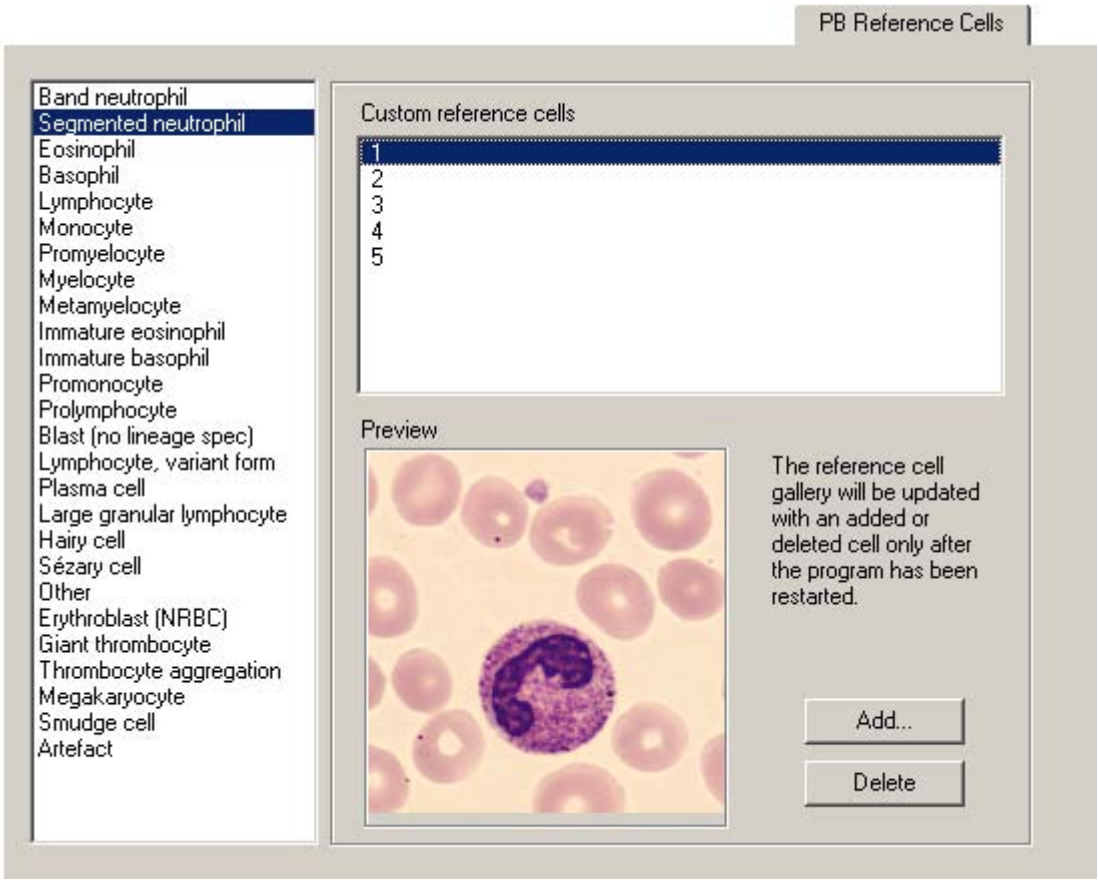
1. Select the standard comment in the list.
2. Click *Delete*.

Modifying a Standard Comment

1. Select the standard comment in the list.
2. Click *Modify* and the *Standard Comments Editor* appears.
3. Edit *Code, Comment type* and *Comment*.
4. Click *OK*.

10.9 Adjusting Reference Cells Settings

Click on a cell class to see a list of all *Custom reference cells* belonging to it. Click on a specific cell to display it in the *Preview* window.

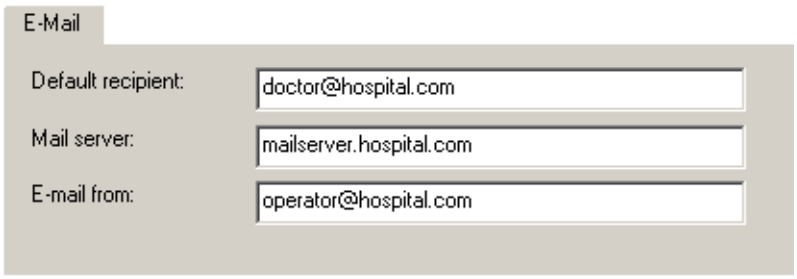


Click *Add* to add custom reference cells from disk. Valid file formats are JPEG (".jpg") and bitmap (".bmp"). All cell images will be stored in the JPEG format. You can also store cells from processed slides (see "Right-click Menu" in 3.1.2 Reclassifying White Blood Cells) as custom reference cells.

Click *Delete* to remove the selected custom reference cell.

10.10 Adjusting E-mail Settings

Enter *Default recipient* of e-mail, specify *Mail server* and *E-mail from*, i.e. sender of e-mail.



10.11 Adjusting Archiving Settings

For storage safety reasons and limited hard disk capacity, it is recommended that you regularly archive the cell images or delete the orders. When you archive, the cell images and comments are transferred from the database to a CD or a hard disk. However, if you delete an order with archived images, you will not be able to access these images again.

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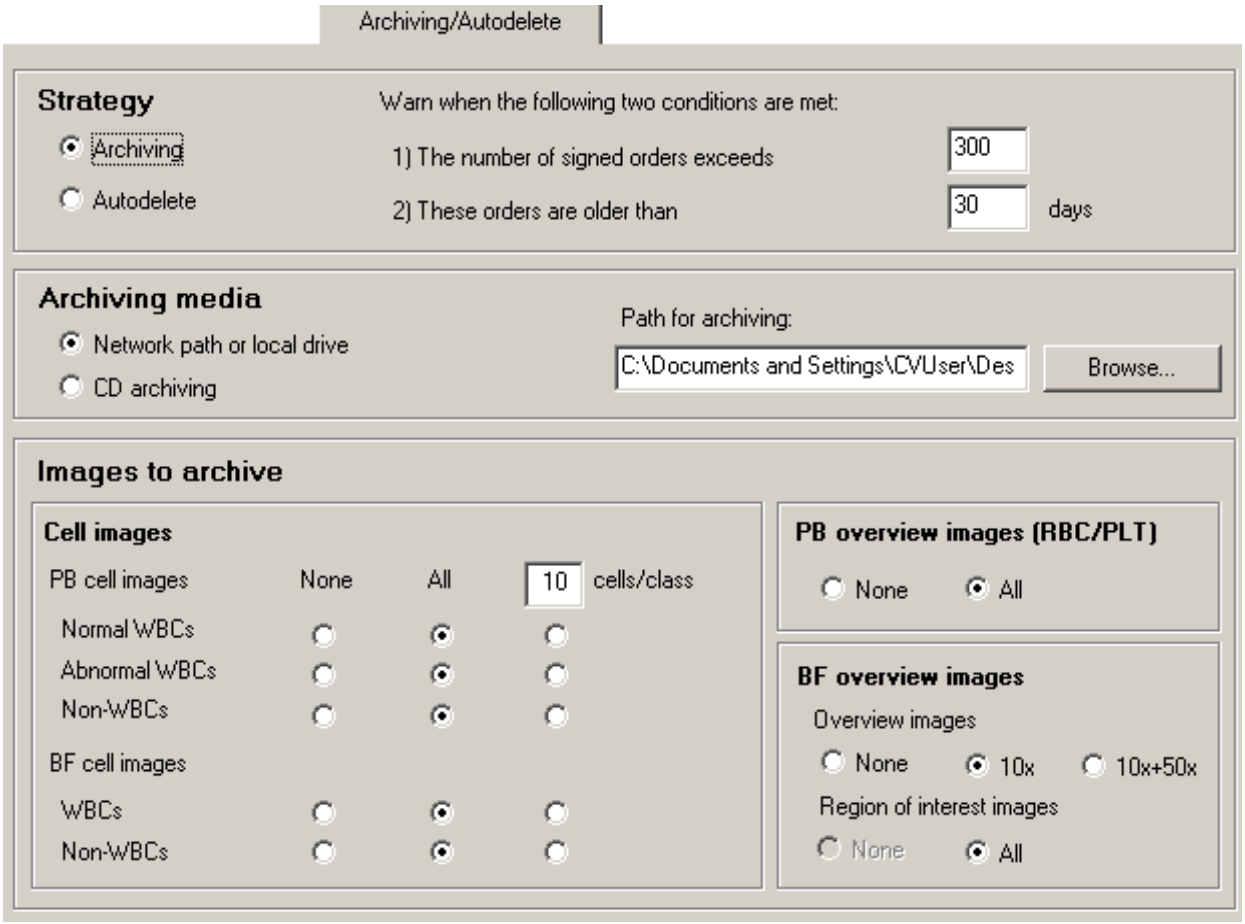

Note! *Only images from signed slides can be archived.*

Orders Archiving Strategy

The archiving strategy depends on your daily throughput and the need for saving images for future use. The autodelete/archiving settings are database specific, enabling each database to have its own archiving strategy.

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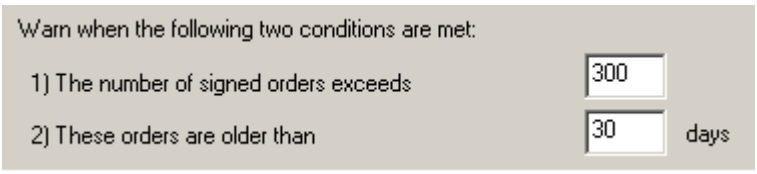
1. Autodelete (*Autodelete instead of archive*, activated)


Warn when the following two conditions are met:
1) The number of signed orders exceeds
300
2) These orders are older than
30
days

All signed orders are permanently deleted when the time has expired. However, autodelete will not begin until the specified number of candidates has been reached.

Example: With the setting above, autodelete will not begin until there are 300 orders older than 30 days.

2. Archive images (*Autodelete instead of archive*, deactivated)

Keep locally at least: Specify the minimum number of days that images from signed slides shall be stored.

Warn when candidates reach: Specify the minimum number of non-archived signed orders at which the program shall prompt the user with a warning message

Archive Media

Select your archive media

- CD Archiving
- Network path or local drive

Archived Images

The images are divided into groups. Use the radio buttons to archive either a certain number of images from each cell class in a group, or all available images, or no images at all from a group.

(Cont'd)

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PB Cell images
Overview images: RBC and PLT

Normal cells:

Segmented neutrophils	Monocytes	Basophils
Lymphocytes	Eosinophils	

Abnormal cells:

Band neutrophils	Lymphocytes variant forms	Prolymphocytes
Promyelocytes	Plasma cells	Large granular lymphocytes
Myelocytes	Immature eosinophils	Hairy cells
Metamyelocytes	Immature basophils	Sézary cells
Blast cells	Promonocytes	User defined WBCs

Non-WBCs:

Other	Giant thrombocyte	Smudge cell
Not classed	Thrombocyte aggregation	Artefacts
Erythroblast (NRBC)	Megakaryocyte	User defined Non-WBCs

BF Cell Images
Overview images: 10x overview images and 50x overview images.

Region of interest images: regions of interest tagged by the user.

WBCs:

Neutrophils	Eosinophils	Lymphocytes
Macrophages	Other	User defined WBCs

Non-WBCs:

Smudge cell	Artefacts	User defined Non-WBCs

Archiving Recommendations

It is recommended to keep the size of the database around 20 GB for optimal database performance.

Always combine archiving with a backup of the database (see 6.6.1 System Backup). The database contains the path to the archived images. If a hard disk crash occurs, it will not be possible to restore the archived images, unless a backup exists.

Note! *Select Compress Database to view the database size (see* 10.1.5 Compressing a Database*).*

Hard Disk Space Requirements Peripheral Blood

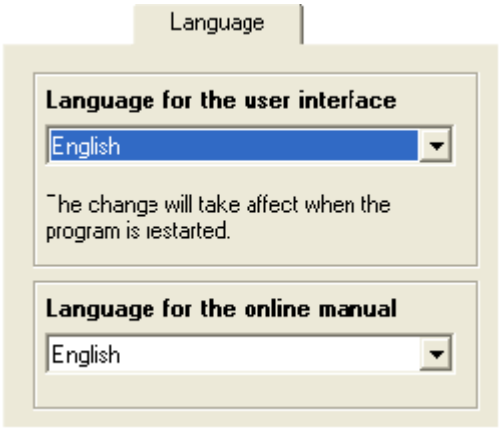
A processed slide with 100 WBCs collected will require about 5 MB of hard disk space. RBC and PLT use the same overview image and will require about 1 MB. A processed slide with 100 WBCs and RBC and/or PLT ordered will require about 6 MB of hard disk space.

Hard Disk Space Requirements Body Fluids

A processed slide with 100 WBCs collected will require about 5 MB of hard disk space. For an analysis area with a diameter of 6mm the10x overview images require about 15 MB and 50x overview images require about 130 MB. A processed slide with 100 WBCs, 10x and 50x overview images ordered will require about 150 MB of hard disk space (6 mm analysis area). Increasing the analysis area from 6 mm to 8 mm will require 78% more disk space for the overview images.

10.12 Adjusting Language Settings

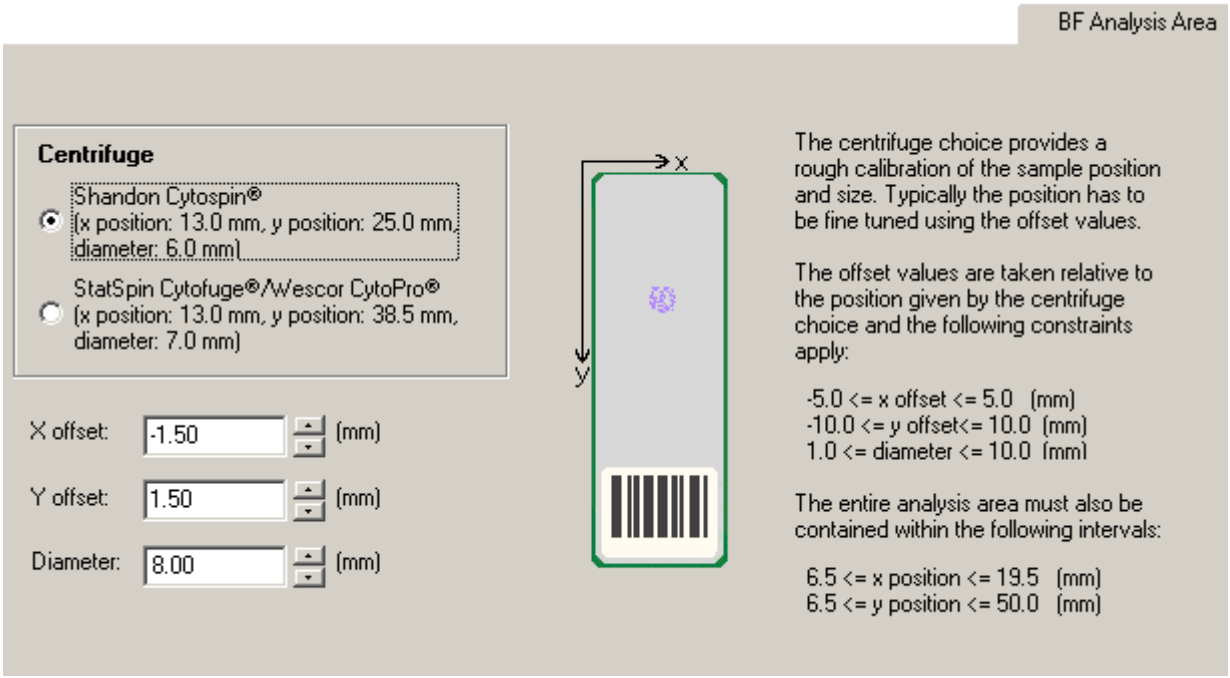
In the *Language* tab you set language for the user interface and manual.



10.13 Adjusting BF Analysis Area

10.13.1 Centering the Analysis Area

Before using the system for the first time or when necessary, define the sample spot location. This is done in *Tools/Settings/BF Analysis Area*.


BF Analysis Area
Centrifuge
Shandon Cytospin®
(x position: 13.0 mm, y position: 25.0 mm,
diameter: 6.0 mm)
StatSpin Cytofuge®/Wescor CytoPro®
(x position: 13.0 mm, y position: 38.5 mm,
diameter: 7.0 mm)
X offset: -1.50 (mm)
Y offset: 1.50 (mm)
Diameter: 8.00 (mm)
x
y
The centrifuge choice provides a rough calibration of the sample position and size. Typically the position has to be fine tuned using the offset values.
The offset values are taken relative to the position given by the centrifuge choice and the following constraints apply:
-5.0 <= x offset <= 5.0 (mm)
-10.0 <= y offset<= 10.0 (mm)
1.0 <= diameter <= 10.0 (mm)
The entire analysis area must also be contained within the following intervals:
6.5 <= x position <= 19.5 (mm)
6.5 <= y position <= 50.0 (mm)

1. Go to *Tools/Settings/BF Analysis Area* and select the desired setting for *Centrifuge*.
2. Run an analysis of a Body Fluid slide with a representative sample spot location.
3. Go to the *Overview* tab. Use the *Navigation* display to establish whether the analysis area needs to be adjusted.
4. If further adjustments are needed, go to *Tools/Settings/BF Analysis Area* and adjust the *X-offset* and *Y-offset* settings (see example below).
5. Restart the program, delete the order and rerun the slide to verify your new settings.

Note! *It is important to delete the order before the slide is rerun. Otherwise the settings from the previous run will be used, which means that your changes to the analysis area settings will have no effect.*

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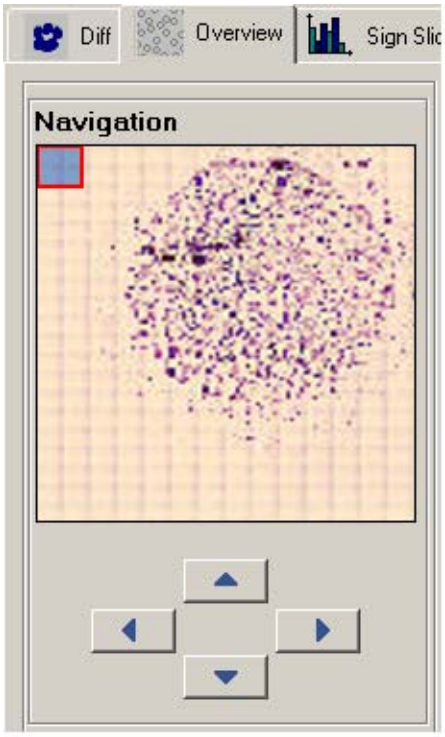
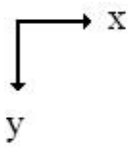
The *Diameter* setting was 8 mm in the example below. In order to center the analysis area on the sample spot, the analysis area needs to be offset by 1.5 mm in the positive x direction and 1.5 mm in the negative y direction.



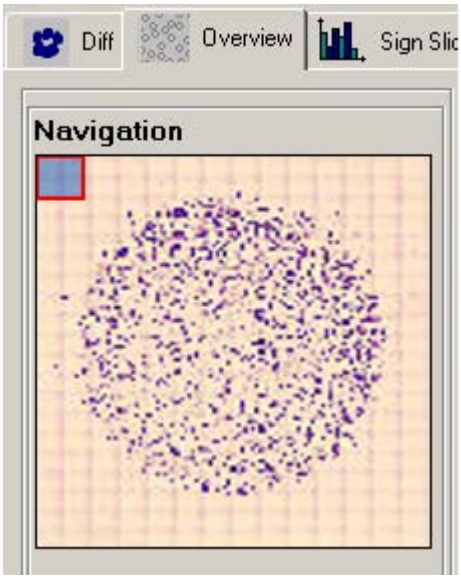


10.13.2 Adjusting the Size of the Analysis Area

To adjust the size of the analysis area, do as follows:

1. Go to *Tools/Settings/BF Analysis Area* and select the desired setting for Diameter.
2. Restart the program, delete the order and rerun the slide to verify your new setting.

As a rule of thumb, the analysis area diameter should be 1mm larger than the sample spot diameter. The slightly larger analysis area diameter will allow for variation in sample spot location between slides. The image below shows an example where the analysis area covers the sample spot well.



Take the last analysis performed and check how well the analysis area covers the sample spot. If the analysis area is too large or too small, go to *Tools/Settings/BF Analysis Area* and adjust the *Diameter* setting.

Note! *Increasing the Diameter setting will increase the processing time.*

11 Quality Control

Self-tests

The system performs self-tests during startup of the software, and at certain points during the operation of the system. When the software starts, the system is checked before the operator can start analyses. During this phase, both the hardware and the software components are tested for anomalies, as well as various requirements for the operation of the system. If the LIS communication is enabled, the program will also check the connection to the LIS.

After each slide the system has processed, it checks the positioning of the microscope objective. While the program is running, the database size is compared intermittently to the rules set for archiving or automatic deletion of old entries, thus ensuring that the database is kept at a reasonable and maintainable size.

The communication with, and response of the hardware, is tested continuously during the operation of the system, and a message will inform the operator if an error occurs during slide processing or other operations on the system.

Cell Location Performance

The Cell location test is used to verify the slide preparation process and the system hardware. The cell location performance shall be verified at regular intervals and after changes in staining procedure or staining solutions by running the Cell location test, see Appendix H — Cell Location. Running the test once or twice a day is a recommended interval at the high-load laboratory.

12 Maintenance

Caution

Be careful not to bend or put excessive force to any part of the system interior.

12.1 Daily Maintenance

1. Make sure there are no magazines in the system.
2. Shut down the system according to the instructions in this manual.
3. Open the main hatch.
4. Clean the XY stage from immersion oil with a lint-free soft cloth.
5. Close the main hatch.

12.2 Weekly Maintenance

12.2.1 Cleaning of Objectives

1. Make sure there are no magazines in the system.
2. Shut down the system according to the instructions in this manual.
3. Open the main hatch.
4. Clean the lens on all objectives by wiping them gently with lens paper. Always use a fresh lens paper to avoid oil contamination. To reach all lenses, carefully turn the objective turret.
5. Apply step 5-11 only on the high power wet objectives. Put a drop of isopropyl alcohol on a piece of crumbled lens paper. Do not use an excessive amount of solvent.
6. Wipe the objective once to remove most of the oil. Do not use a circular motion to clean lenses as this increases the risk of scratching the surface.
7. Take a new piece of lens paper and put a drop of lens cleaner in the middle.
8. Place the lens paper over the objective.
9. Use a cotton swab to gently hold the paper against the objective while you drag the lens paper away from the objective.

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10. The cotton swab should remain over the center of the objective and the lens paper under it should be wet. If the lens paper dries out then repeat starting on a wet (but non-oily) spot on the lens.
11. Repeat once from step 5.

Important

Make sure there is no oil on the low power (10x) dry objective.

Important

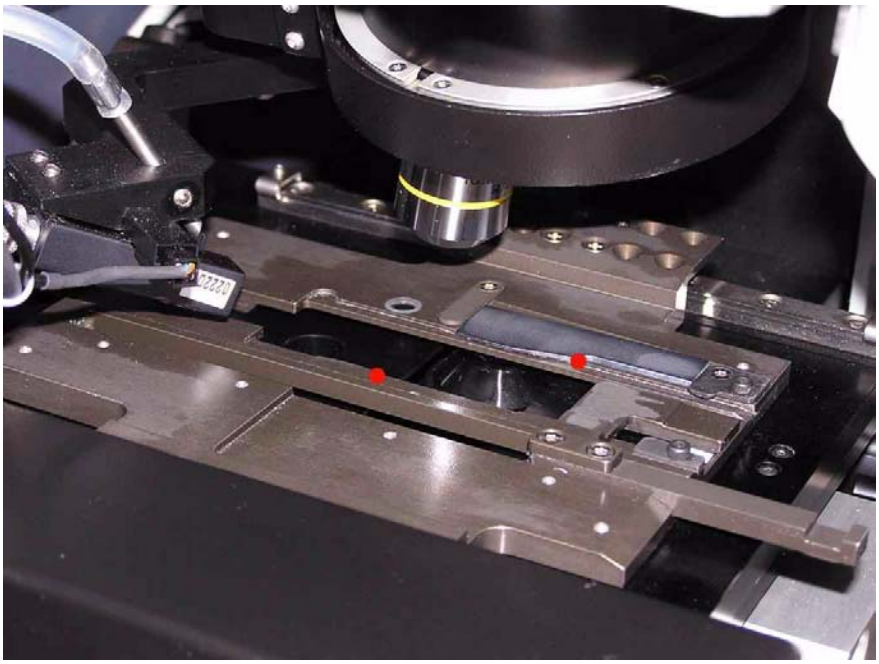
Cleaning with alcohol increases the risk of air bubbles on the objective, which affects the image quality for the first two slides. To avoid the problem, it is recommended to run two slides after weekly maintenance. Delete these slides immediately to avoid the risk of result mix-ups.

Caution

Avoid alcohol on the oil level indicator.

12.2.2 Slide Guides

Clean the slide guides carefully to remove any glass shards or particles. Apply one drop of stage oil at the two positions, marked by red dots in the image below.



12.3 Preventive Maintenance

No preventive maintenance by the user is necessary. Preventive maintenance is to be performed by CellaVision authorized personnel.

12.4 Remedial Maintenance

12.4.1 Immersion Oil Refill

WARNING

The oil may cause sensitization by skin contact. We recommend using gloves.

1. Open the main hatch.
2. Remove the screw cork from the oil canister.

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3. Fill up with specified oil using a clean funnel. Do not fill up above the black line.We recommend not filling up more oil than will be used in 6 months. A full oil canister of 500ml corresponds to about 10000 slides.
4. Clean the system from immersion oil spillage with a lint-free soft cloth.
5. Refit the screw cork.
6. Close the main hatch.

Caution

Use only immersion oil recommended by CellaVision AB (see Appendix A — System Specification).

12.4.2 Bulb Exchange

WARNING

When you exchange a bulb, first switch off the SSU. Wait for the lamp housing and lamp bulb to cool before touching.

1. Loosen the 2 non-detachable screws, which hold the lamp hatch, about half a turn counter clockwise, using a 3 mm Allen key.
2. Remove the hatch by pulling it outwards and then upwards.

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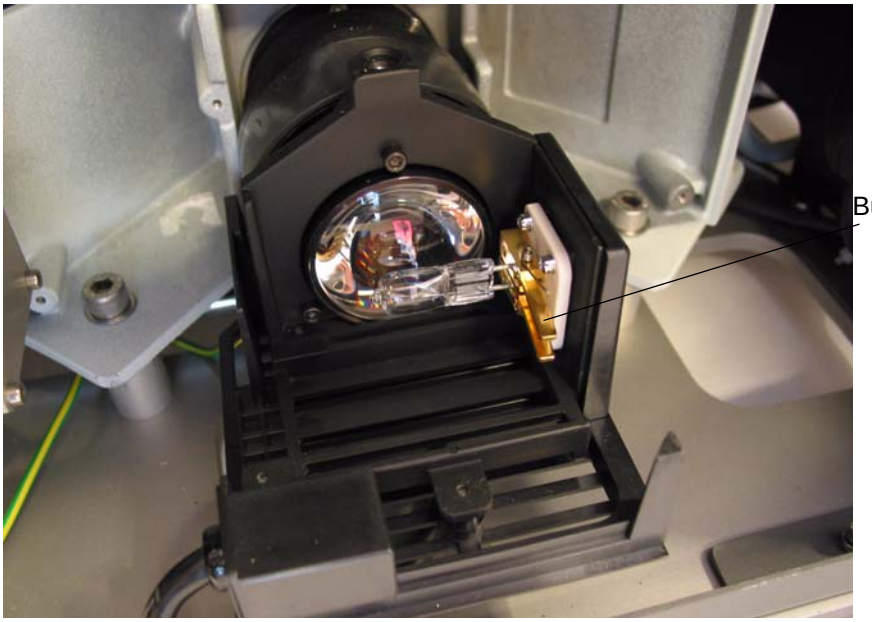
3. Loosen the non-detachable screw of the lamp house cover using a 3 mm Allen key.
4. Lift and remove the cover of the lamp house.



Caution

Do not touch the new bulb with bare hands. If fingerprints are made on the bulb, wipe it with a soft, lint-free cloth.

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5. Press the bulb clamping levers and gently withdraw the old bulb from the lamp housing.
6. Press the bulb clamping levers and fully insert the bulb pins into the pin holes.
7. Gently release the bulb clamping levers to their original position to secure the bulb.
8. Refit the lamp house cover.
9. Tighten the screw of the lamp house cover.
10. Refit the lamp hatch.
11. Tighten the screws of the lamp hatch.

12.5 Database Performance

To maintain a high database performance, it is very important to control the size of the database. It is also recommended to restart the system computer at least once a week.

12.5.1 Controlling the Database Size

A large database will have lower performance (access time, database search time etc.) compared to a smaller database. The size of the database can be controlled by two methods:

1. Activate autodelete of orders.
2. Archive images onto CD-R/RW or LAN.

Recommendation:
Keep the size of the database below 20 GB. See 10.11 Adjusting Archiving Settings for more information.

Note! *Select Compress Database to view the database size (see* 10.1.5 Compressing a Database*).*

13 Troubleshooting

13.1 Troubleshooting Steps

If a problem occurs, follow these steps:

1. Observe any unusual circumstances surrounding the problem.
2. Note any error messages displayed.
3. See 13.2 Troubleshooting Chart to find possible remedies.
4. If the problem persists, contact your distributor for assistance.

13.2 Troubleshooting Chart

13.2.1 General Startup Errors

Problem	Cause	Action
You try to start the program. Message box: The program has already been started and you cannot start another until the previous one is closed.	Previous program has not closed.	Make sure the program is closed. Wait 10 seconds and try again.
Message box: Could not log on to the system. Make sure you typed your username and password correctly.	Wrong username and/ or password.	Enter correct username and password. Note that passwords are case sensitive ("a" and "A" is not the same).
	Caps Lock is activated.	Deactivate Caps Lock.
Message box: Could not log on to the system. Network connection error!	The database server could not be reached.	If the database is stored on the system computer, restart the computer and the program. Otherwise, check the network connection and that the computer that stores the database is turned on.
Message box: Disk space exhausted.	The database is located on the C:\ drive.	Move the database to the E:\ drive.
Logging on to the system is slow.	The database server needs to be restarted.	Restart the system computer, or the computer on which the database resides.
	The database is too large.	Keep the database size at the recommended level (see 12.5 Database Performance).
	The database files are fragmented.	Compress the database (see 10.1.5 Compressing a Database).

13.2.2 Hardware Startup Errors

Problem	Cause	Action
In startup test: <LIS Communication Server ERROR: No contact could be established with remote LIS server!>	LIS cable is disconnected.	Make sure that the cable to the LIS is connected. Restart the program.
In startup test: Camera 1394 Communication Server. Could not initialize camera. Please check camera cable.	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the program.
In startup test: Instrument Communication Server. -SSU error. No connection with the CCU. ERROR: Initialization failed.	No connection between the SSU and the system computer.	Check the connection between the SSU and the system computer. Restart the system and program.
The yellow status lamp is not lit even 30s after power on.	The status lamp is not working.	Contact your local vendor's technical support.
The yellow status lamp is flashing but the startup test was successful.	The oil level is low.	Fill up the oil canister.
The yellow status lamp is flashing and the startup test fails on System Control Server.	One of the hatches is not closed.	Make sure all hatches are closed and restart the program.
	There was a jam.	Remove any magazines and slides (see 13.2.10 Slide Transport Jam). Restart the SSU and the program. If error persists, Contact your local vendor's technical support.
	The output drawer is full and there is a magazine waiting to be moved into the drawer.	Check that no magazine is positioned to the far right in the output drawer. Restart the SSU and the program.
The green power on lamp is never lit.	The power is out for the SSU.	Connect the power cable and try again.
	The power on lamp is not working,	Contact your local vendor's technical support.

13.2.3 General Processing Problems

Problem	Cause	Action
Start is deactivated.	No magazines on the conveyer.	Add magazines (see 2.5.1 Adding Magazines).
	One or more hatches are open, indicated by:	Close all hatches. See Appendix C — Buttons and Indicators for Hatch Indicators.
	An error has occurred during slide processing.	Restart the SSU and the program.
Slide process does not start, even though Autostart is selected.	No magazines on the conveyer.	Add magazines (see 2.5.1 Adding Magazines).
	One or more hatches are open, indicated by:	Close all hatches. See Appendix C — Buttons and Indicators for Hatch Indicators.
	System status is Idle or Stopped.	Click Start.
WBC images are not centered on the cell, but the cell can still be seen.	System needs calibration or alignment.	Contact your local vendor's technical support.
Slide status: Incomplete analysis Less than the ordered number of cells are collected.	Too small monolayer found.	Prepare the slides with longer blood films.
	Artefacts (staining precipitates) on the slide.	Make sure that the solutions are changed according to the recommendations in Appendix G.
	Dust on objectives.	Perform weekly maintenance on the current objective (see 12.2 Weekly Maintenance)
	High power cell images are not centered.	See the trouble shooting sections above.'
	Oil or dust on the low power objective.	Perform weekly maintenance on the current objective (see 12.2 Weekly Maintenance)
	The microscope lamp is defective.	Replace the lamp (see 12.4.2 Bulb Exchange).

	System needs calibration or alignment.	Contact your local vendor's technical support.
Slide status: Incomplete analysis Could not find RBC monolayer	Oil on the slide.	Clean the oil off the slide and process it again.
Slide status: Analysis failure View the *Slide Information* dialog for more details.	No monolayer found.	Make sure that the slides are prepared according to the recommendations in Appendix G.
	Oil on the slide.	Clean the oil off the slide and process it again.
	Oil or dust on the low power objective.	Perform weekly maintenance on the current objective (see 12.2 Weekly Maintenance)
Slide status: Light error when using 10x/50x/100x magnification	Dirty objective.	Perform weekly maintenance on the specified objective (see 12.2 Weekly Maintenance)
	Too dark specimen.	Make sure that the slides are prepared according to the recommendations in Appendix G.
	Condenser is dirty	Clean condenser
	The microscope lamp is defective.	Replace the lamp (see 12.4.2 Bulb Exchange
High power images are not in focus.	Dust on the objective.	Perform weekly maintenance on the current objective (see 12.2 Weekly Maintenance
	Incorrect objective settings.	Contact your local vendor's technical support
Message box: Critical internal error.	Temporary software error.	Restart the SSU and the system computer.
Message box: An error occurred during oil dispensing. Check the oil level. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The oil canister is empty.	Refill oil canister.
	There are air bubbles in the oil hose.	Restart the SSU, run a slide. Repeat until there are no air bubbles in the oil hose.

Seemingly normal slides get slide status: Empty or no slide PID.	The barcode reader is not connected.	Check the cabling of the barcode reader.
	No barcode found.	Check positioning and size of the barcode (see Appendix A — System Specification).
	The barcode could not be read due to bad print quality.	Clean the barcode printer head.
		Replace the printer ribbon on the barcode printer.
Message box: Critical error, no connection with the database.	Connection with the database has been lost.	Check network connection. Restart the system computer, or the computer on which the database resides.
Message box: Verify that the following hatches are closed:	At least the hatch specified in the message box is open.	Close all open hatches and click Retry.
Database access is slow.	The database server needs to be restarted.	Restart the system computer, or the computer on which the database resides.
	The database is too large.	Keep the database size at the recommended level (see 12.5 Database Performance).
	The database files are fragmented.	Compress the database (see 10.1.5 Compressing a Database.
Body fluid sample spot is not centered	Incorrect configuration of BF analysis area	Configure the BF analysis area settings (See 10.13 Adjusting BF Analysis Area).
	The sample spot location varies too much between samples.	Make sure your sample preparation process produces slides where the sample spot is always in the same location.
The analysis area does not cover the entire body fluid sample spot.	Incorrect configuration of BF analysis area	Configure the BF analysis area settings (See 10.13 Adjusting BF Analysis Area).
Seemingly normal scan slides get slide status: Analysis failure, with the additional information: No image data in scanned area	Too little specimen on the slides.	Prepare a slide with more specimen.
	Wrong area selected.	Select the correct area and process the slide again.

13.2.4 Hardware Errors During Processing

Problem	Cause	Action
Message box: Critical jam error.	At least the motor specified in the message box reported a jam error.	Remove any magazines and slides (see 13.2.10 Slide Transport Jam). Restart the SSU and the program. If error persists, contact your local vendor's technical support.
	Magazine is broken, and fragments are blocking the slide.	Remove any magazines and slides (see 13.2.10 Slide Transport Jam). Load the slides to a new magazine. Restart the SSU and the program. If error persists, contact your local vendor's technical support.
	The barcode could not be read after the slide was processed.	Wipe off oil from the barcode label.
Message box: Critical calibration error.	At least the motor specified in the message box reported a jam error.	Remove any magazines and slides (see 13.2.10 Slide Transport Jam). Restart the SSU and the program. If error persists, Contact your local vendor's technical support.
Message box: Critical temperature error.	Critical temperature in the SSU.	Shut down the SSU and contact your local vendor's technical support.
Message box: Critical communication error.	No connection between the SSU and the system computer.	Check the connection between the SSU and the system computer. Check power connection to the SSU. Restart the system and the program.
Message box: Magazine infeed error. Remove the magazine if it is stuck. Restart the system. If the problem persists, see troubleshooting section in the User's manual.	The magazine is stuck.	Remove the magazine (see 13.2.11 Magazine Transport Jam). Restart the SSU and the program.
Message box: Positioning failure when reading the slide barcode. Remove the slide if it is stuck or broken. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The slide is stuck or broken.	Remove the slide (see 13.2.10 Slide Transport Jam). Restart the SSU and the program.

Message box: Positioning error when moving the slide from the magazine into the slide holder. Remove the slide if it is stuck or broken. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The slide was stuck, broken or fell out during transport to the slide holder.	Remove the slide (see 13.2.10 Slide Transport Jam). Restart the SSU and the program.
Message box: Positioning error when moving the slide from the slide holder into the magazine. Remove the slide if it is stuck or broken. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The slide was stuck, broken or fell out during transport back into the magazine.	Remove the slide (see 13.2.10 Slide Transport Jam). Restart the SSU and the program.
Message box: Magazine eject error. Remove the magazine if it is stuck or broken. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The magazine is stuck.	Remove the magazine (see 13.2.11 Magazine Transport Jam). Restart the SSU and the program.
	Slides are not fully inserted into the magazine since it is worn out.	Push the slides back into the magazine. Restart the SSU and the program. Discard the worn out magazine.

Message box: An error occurred when changing objectives. Make sure that nothing is preventing the objective rotation. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	Some object prevents changing of objectives.	Remove the object that prevents changing of objectives. Rotate the objectives by hand to make sure that nothing is preventing the objective rotation. Restart the SSU and the program.
Message box: Positioning error occurred when calibrating the motors. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual. The error was reported for the following motors:	Something prevents motor movement during calibration of motors.	Remove the obstacle that prevents motor movement. Restart the SSU.
Message box: Temperature too high in the Control Unit. Shut down the system. Check that the air filter on the back of the SSU (slide scanning unit) not is dirty. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The air filter is dirty.	Check that the air filter on the back of the SSU is not dirty.
	The fan in the control unit does not function.	The fan has to be exchanged.

Message box: Communication error between the system computer and the SSU (slide scanning unit). Reconnect the network cable between the system computer and the SSU. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	Network cable between the system computer and the SSU is disconnected.	Reconnect the network cable. Restart the SSU and the program.
	Network card in the SSU or system computer is broken.	The network card has to be exchanged.
Message box: This operation can not be performed at this time. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	Communication error between SSU and system computer.	Restart the SSU and the program.
Message box: No camera found. Check cable between the camera and the system computer. Restart the software. If the problem persists, see the troubleshooting section in the User's manual to solve this problem.	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the program.
Message box: Camera initialization error. Check cable between the camera and the system computer. Restart the software. If the problem persists, see the troubleshooting section in the User's manual to solve this problem.	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the program.

Message box: Connection with the camera lost. Check cable between the camera and the system computer. Restart the software. If the problem persists, see the troubleshooting section in the User's manual to solve this problem.	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the program.
Message box: The configuration of the Control unit is incorrect. Please contact support.	The Control unit has lost its configuration.	Contact your local vendor’s technical support.
Message box: File system or registry error. Restart the system. If the error persists see troubleshooting section in the User's Manual.	The File system or registry is corrupt.	Reinstall the program.

13.2.5 LIS Errors

Problem	Cause	Action
Slide status: Default values The slides are analyzed with default values even though LIS is used for order information.	The orders are not in the LIS.	Make sure that orders for the slides that are to be processed are already available in the LIS.
	The connection to the LIS is broken.	Make sure that the cable to the LIS is connected.
LIS status:	The connection to the LIS has been broken.	Make sure that the cable to the LIS is connected. Results are automatically resent when connection is established.

13.2.6 Archiving Errors

Problem	Cause	Action
Message box: There was a general error when accessing the recorder. Check error logs.	If a problem occurred previously while trying to archive, it may be that the recorder has not been unlocked.	Restart the system computer and the program and try archiving again.
Message box: The chosen location for the temporary archive files used for burning does not have enough space. Free up space at the location and try again.	The volume or media chosen to store the temporary (when recording to CD) or actual archive does not have enough room left.	Contact your Administrator. Free up space for the temporary image. NOTE: When archiving to LAN or a hard drive on the computer, the archiving wizard requires at least 1 Gb. If CD recording is used, the archiving wizard requires 3 times the capacity of the CD in temporary working space (i.e. for a 650 Mb disc, 1950 Mb of free space is required).
Automatic deletion is enabled instead of archiving, and the deletion starts, but does not delete any or all of the older orders matching the criteria.	A database exception occurred, either due to an error in the database, or due to a transaction conflict when a CellaVision remote review opens an old order just as it is about to be deleted.	Try setting the limit on the number of orders matching the criteria for automatic deletion lower (zero) and let the program start the deletion again. You can also sort the orders in the database and try to delete them manually.

13.2.7 Cell Location Problems

Cell Location Problems Peripheral Blood

Problem	Cause	Action
Too many non-nucleated cells.	Too many smudge cells.	Run another slide with less smudge cells.
		Verify smear preparation process.
	Too many artefacts.	Increase wash step
		Filter the stain.
		Ensure that the stain has not exceeded the expiration date
	Cells misclassified as non-nucleated cells.	Run another slide and if the problem remains prepare new staining solutions.
Too few nucleated cells located.	Low WBC count	Prepare a new slide with a higher WBC count.
	Too short smear.	Prepare longer smears.
	Poor smear quality.	Verify smear preparation procedure.
Nearly all boxes are far from the cells.	Stage or calibration error.	Contact your local vendor’s technical support.
Too many missed cells.	Too high WBC count	Do not process slides with a WBC count that exceeds $100x10^9$/l.
	Poor staining.	Verify staining procedure.
Long processing time.	Low WBC count.	Prepare a new slide with a higher WBC count.
	Poor staining.	Verify staining procedure.

Cell Location Problems Body Fluids

Problem	Cause	Action
Too many non-WBCs.	Too many smudge cells.	Run another slide with less smudge cells.
		Verify sample preparation process.
		Decrease centrifuge speed.
	Too many artefacts.	Increase wash step
		Filter the stain.
		Ensure that the stain has not exceeded the expiration date
	Cells misclassified as non-nucleated cells.	Run another slide and if the problem remains prepare new staining solutions.
Too few WBCs located.	Few WBCs in sample	Use a larger sample volume.
Nearly all boxes are far from the cells.	Stage or calibration error.	Contact your local vendor's technical support.
Too many missed cells.	Too many WBCs in the sample	Do not process slides where the number of WBCs exceeds the recommended amount.
	Poor staining.	Verify staining procedure.

13.2.8 Barcode Problems

Problem	Cause	Action
The barcode could not be read.	Blurry barcode, caused by immersion oil on the barcode.	Make sure the barcode is resistant to immersion oil.
		Print the barcode as defined in Appendix A — System Specification.
	There is no quiet zone.	Make sure there is a quiet zone according to specifications (and that the barcode is not printed too close to a logotype, if applicable)
	Symbology contrast is too low.	Adjust the printer.
		Use slides with a white, smooth, frosted area.
	The barcode is damaged (barcode cells are missing).	Adjust the printer.
		Use slides with a white, smooth, frosted area.
Critical error in the database.	The Order ID contains more than 24 characters.	Do not use an Order ID with more than 24 characters.
Could not find the order in the LIS.	Leading spaces in the Order ID.	Remove leading spaces in the Order ID.
		Also see section 12.2.5 for LIS errors.

13.2.9 Staining Problems

Problem	Cause	Action
The red cells appear bright red, the white cells will appear indistinct with pale blue rather than purple nuclei, and brilliant red eosinophilic granules will be seen microscopically.	Understaining.	The fixation and staining time may be increased.
	Overwashing.	The washing technique may be corrected so that it is adequate but not excessive.
	Use of stain, buffer or wash water that is too acidic.	The pH of the buffer may be checked with a pH meter and adjusted.
	The increased acidity is due to exposure of the stain or buffer to acid fumes.	Use a new batch of stain or buffer.
Pale, inadequately-stained red cells, nuclei or eosinophilic granules.	Understaining.	The fixation and staining time may be increased.
	Overwashing.	The washing technique may be corrected so that it is adequate but not excessive.
The erythrocytes appear blue or green, the nuclear chromatin is deep blue or black and the granules of the neutrophilic granulocytes are deeply overstained and appear large and prominent. The granules of the eosinophils are blue or gray.	Overstaining.	Decrease the fixation time.
		The amount of stain used may be decreased (shorten the staining time) and the amount of buffer increased (increase the stain/buffer time).

	Inadequate washing.	Increase the wash step.
	Too high an alkalinity of stain or buffer.	The pH of the buffer may be checked with a pH meter and readjusted to a lower pH.
	Thick blood smears.	Prepare a thinner blood smear.
Samples have dark areas of stain or other artefacts.	Drying is occurring during the period of staining.	Ensure the adequate drying of samples previous to staining.
	Unclean slides.	Use clean slides.
	Inadequate washing (not washing enough to remove the metallic scum).	Increase wash step.
	A stain is forming precipitate in the solution.	Filter the stain.
		Ensure that the stain has not exceeded the expiration date

13.2.10 Slide Transport Jam

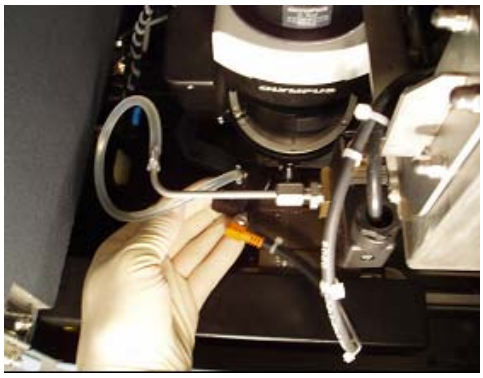
WARNING

Always turn the system mains off before interacting with the interior of the system.

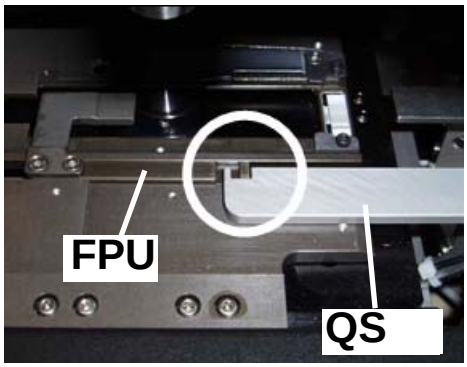
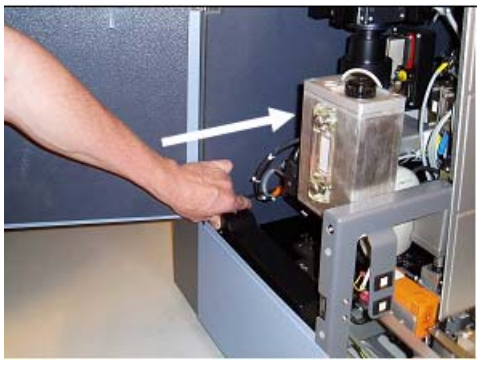
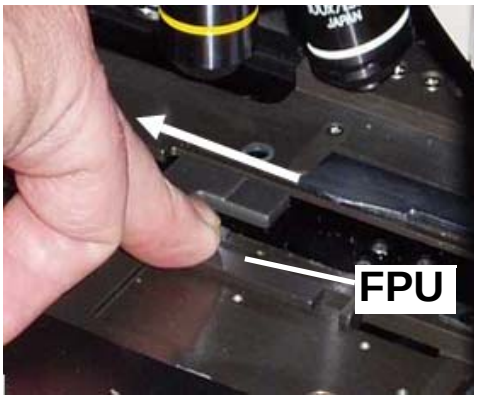
WARNING

A broken slide can cause serious cuts and poses a danger of infection. Always use protective gloves and tweezers when removing glass shards from the system.

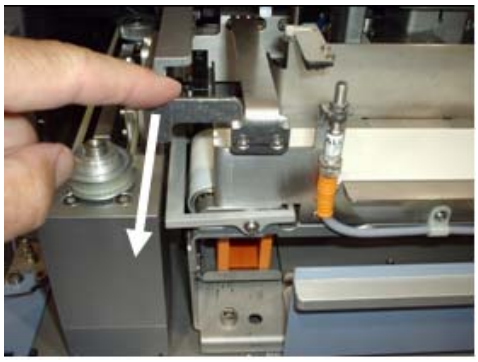
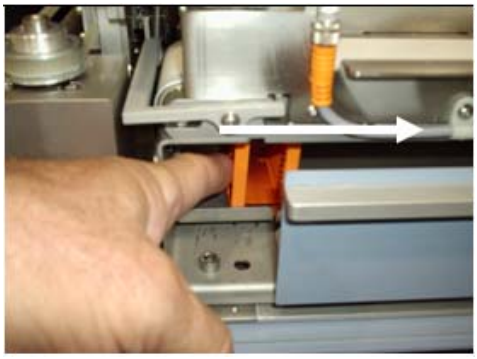
 	1.Turn off the power to the SSU. 2.Open the Main hatch. 3.Open the Service hatch.
	4.Gently, pull the slide into the magazine by moving the QS arm straight back. If the slide does not move, lies loose or is broken, remove it by hand. 5.Gently pull the QS arm all the way in the direction indicated by the arrow. 6.Close all hatches and restart the system. The magazine will be ejected into the output drawer.

	If the jammed slide is on the XY-stage, move the immersion oil arm out of the way.

13.2.11 Magazine Transport Jam

	1.Turn off the power to the SSU. 2.Open the Main hatch. 3.Open the Service hatch. 4.Look on the stage. If the QS arm and the FPU are connected, as shown in the picture, proceed to step 5. Otherwise, proceed to step 6.
	5.Place your hand as shown in the picture. Push gently in the direction of the arrow until the FPU and the QS arm are disconnected.
	6.Gently slide the FPU fully onto the stage in the direction of the arrow.

	7.Gently pull the QS arm in the direction of the arrow until it stops.
	8.Move the lift down by turning the coupling to the drive screw.
	9.When the QS arm can clear the top of the magazine, stop turning the coupling and gently push the QS arm in the direction of the arrow until it is in contact with the magazine.
	10.Continue turning the coupling until, while looking through the Output Drawer, the magazine is level with the floor.

	11.Gently pull the QS arm in the direction indicated by the arrow until the magazine stops.
	12.Push the magazine onto the Output Drawer. 13.Open the Output Drawer and remove the magazine.
	14.Gently pull the QS arm in the direction of the arrow until it stops. 15.Close all the hatches and restart the system.

Appendix A — System Specification

Climate Specification

CellaVision® DM96 is designed to be safely operated at 18 °C to 31 °C (64 °F to 88 °F), at a maximum relative humidity of 90% with no condensation allowed, indoor use and altitudes up to 2000 m.

Physical Specification

Weight: 60 kg, excluding PC and monitor
Size (WxDxH): 53x58x62 cm, 20.9x23.6x24.8 inches

Electric Specification (monitor not included)

Voltage input: 100-240 VAC
Current input for the system computer: 6-3A
Current input for the slide scanning unit: 2-1A
Total current input for the system: 8-4 A
Voltage frequency: 50/60 Hz
Pollution degree: 2
Installation category: II
Over voltage category: II
Mains supply voltage fluctuations not to exceed ± 10 percent of the nominal voltage.

WARNING

Connect to ground sockets only.

WARNING

The mains supply cord and plug of the equipment shall comply with any national regulations.

WARNING

External computing devices connected to the communication connector (LAN) of the system have to comply with the standard UL 60950.

(Cont'd)

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Performance Specification Peripheral blood

Average WBC cell-location and display of at least 97 % with a standard deviation less than 2 %.
Throughput: Approximately 30 slides/h for complete orders containing RBC, PLT and 100-cell WBC.

Results of short-term imprecision found in a clinical evaluation on 219 patient samples, based on NCCLS standard H-20A:

Cell class	SD (%)	Cell class	SD (%)
Segmented neutrophils	4.7	Basophils	0.7
Band neutrophils	3.0	Lymphocytes	5.0
Eosinophils	1.2	Monocytes	2.0

Limitations: Distinctions between band and segmented neutrophils, metamyelocytes and myelocytes, myelocytes and promyelocytes, lymphocyte and lymphocytes variant forms are subjects to variations among individual operators.

Performance Specification Body Fluid

Average WBC cell-location and display of at least 97 % with a standard deviation less than 2%.
Throughput: Approximately 20 slides/h for orders containing only 10x overview images (6 mm analysis area). Approximately 6 slides/h for orders containing both 10x and 50 overview images (6 mm analysis area).

Results of short-term imprecision found in a clinical evaluation on 156 samples, based on NCCLS standard H-20A*:

Cell class	**SD (%)**	**Cell class**	**SD (%)**
Neutrophils	3.4	Macrophages	6.3
Eosinophils	0.8	Other	2.2
Lymphocytes	6.0		

* The following fluid types were not included in the evaluation: pericardial, abdominal, drain, CAPD and bronchoalveolar lavage.

Performance Specification Scan

Throughput data and disk space requirements for the scanned slides:

Analysis area size	Overview images	Processing time	Disk space
5x5 mm	10x	1 min	10 MB
5x5 mm	10x+50x	8 min	130 MB
10x10 mm	10x	2 min	45 MB
10x10 mm	10x+50x	30 min	500 MB

The given values are approximate. Processing time and required disk space vary depending on the sample.

Materials Specification

Immersion oil: Trak 300™ Automated Differential System Immersion Oil. Refractive index 1.5150. Viscosity 300 cSt. PCB free. 500ml should be sufficient for approximately 10000 analyses.

Bulb: OSRAM XENOPHOT HLX 64625 FCR 12 V 100 W halogen.

CellaVision slide magazines.

Stain: May Grünwald Giemsa or Wright.

Slide requirements (mm): glass, 75.0-76.0 x 25.0-26.0 x 0.9-1.2, ground edges, clipped or round corners, frosted end.

Note! *CellaVision DM96 analyzers with a serial number higher than 31216 or systems that have been upgraded with the Stage Upgrade Kit (CellaVision Part number XU-10043) support slides with the following dimensions (mm): 75.0-76.0 x 25.0-26.3 x 0.9-1.2*

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Slide descriptions:

Clipped corners Round corner

Images provided by Erie Scientific (www.eriesci.com)

Caution

Use only clipped/round corner slides. Failing to do so may cause jams and excessive wear on magazines and the system.

Caution

Using the magazines more than 100 times may damage the system.

Barcode

The system requires high quality barcode labels on the slides. Maximize the barcode width for best result.

Note! *The magazines are supplied with barcode labels. If you replace the barcode label, the new barcode must not contain the '/' character.*

Linear Barcode Scanner

The following barcode formats are accepted by the system:

UPC-A	Interleave 2 of 5	CODE 11
UPC-E	Industrial 25	China Postage
EAN-13	Matrix 25	MSI/PLESSEY
CODE 39	CODABAR/NW7	CODE 32
CODE 128	CODE 93	BC412

The minimum barcode resolution shall be 7 mil.

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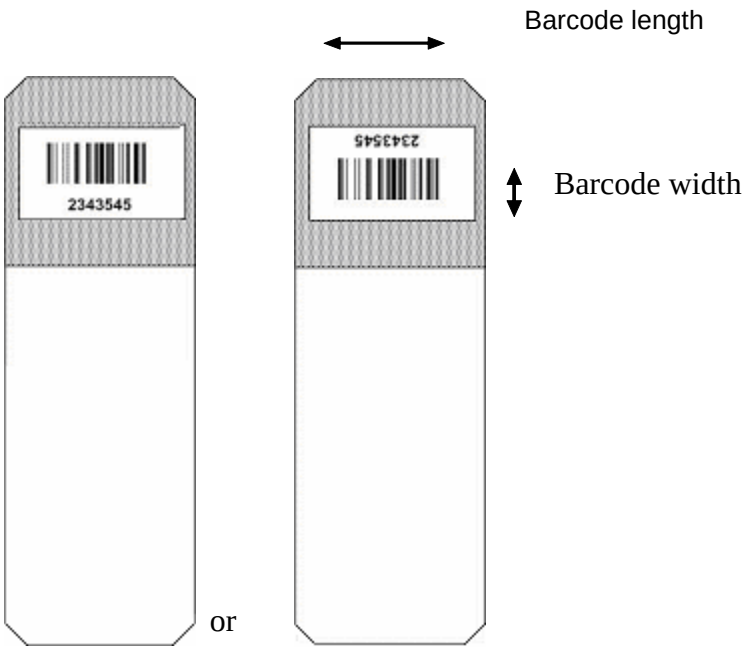
The label should be positioned as shown in the figure below. The edges of the label shall be at least 1 mm from the edges of the slide.

Note! *Avoid oil on the slide label.*



2D-D Barcode Scanner

The following barcode formats are accepted by the system:

Linear codes			
CODE 39	CODABAR/NW7	Code 128	Interleave 2 of 5
2D-D codes			
DataMatrix	QR		

(Cont'd)

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Requirements

Sample ID

When using either a DataMatrix or a QR code the only information allowed in the code is a sample ID (i.e. no other data), which may be at most 24 characters long but which may be padded with spaces (ASCII code 32). No leading spaces are allowed.

Print quality

The printed barcode shall be resistant to immersion oil and be printed with a high contrast ratio between background and the printed barcode. If the barcode is printed directly onto a slide, it must be printed on a white, smooth, frosted area of the slide.

Barcode size

The minimum supported barcode resolutions are listed in the table below.

Supported code resolution	
Code	**Cell size, mil**
QR	13
DataMatrix	9
Code 39	7
Code 128	7
Codabar/NW7	7
Interleave 2 of 5	7

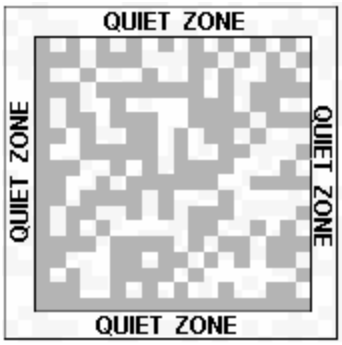
(Cont'd)

(Cont'd)

Quiet zone

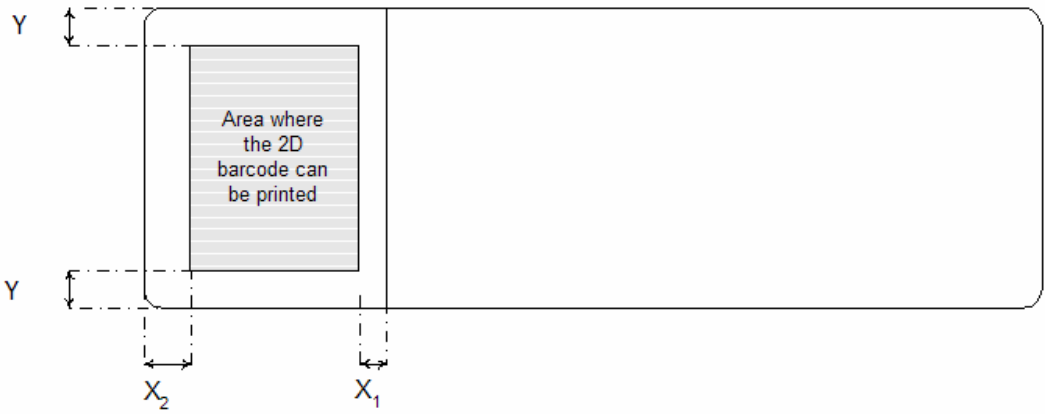
The recommended quiet zone is listed in the table below.

Symbology	**Vertical quiet zone, cells**		**Horizontal quiet zone, cells**	
	Top	Bottom	Top	Bottom
DataMatrix	1	1	1	1
QR	4	4	4	4



Barcode position

The barcode shall be positioned within the area as illustrated in the figure below.



Where

X1 > 2 mm; X2 > 6mm; Y > 4mm

Firefighting Procedures

Fire and explosion hazard:

Flash point: >300ºF / 149ºC

Upper explosive limit: N/A

Lower explosive limit: N/A

Fire fighting media: Carbon dioxide, Foam, dry chemical, and waterfog.

Fire response procedures: Fire fighters must use self-contained breathing apparatus.

Unusual fire and explosion hazards: Containers should be kept cool in the event of fire.

Appendix B — Storage and Handling

Storage

The system shall be stored within the following climate condition: 10 °C to 40 °C (50 °F to 104 °F), at a maximum relative humidity of 80% with no condensation allowed.

Transporting the System

The system shall be packaged, transported and unpacked by CellaVision authorized personnel/carrier only. We recommend saving the package for possible future transports.

Disposal Information

Magazines: As combustible plastics (PC + ABS).
The system: Please contact your distributor.

Appendix C — Buttons and Indicators

If you place the mouse-pointer over the buttons or indicators, you can view tool tips in the Status bar (bottom left-hand corner).

Buttons

	CellaVision® DM software	
	System Control View	F4
	Database View	F5
	Verification View	F6
	Report View	F7
	Close Order and Slide	
	Order Data	
	Help Lines	Enables help lines for PLT estimate.
	Confirm Cell Counter Results	
	Comments	
	WBC Full Screen View	
	WBC Galleries	
	Zoom Mode	
	Zoom In/Zoom Out	
	Scroll Mode	

	Color/Brightness	Adjusts image color and brightness.
	Toggle Color/Brightness	Toggles between default color and lights settings and personal settings.
	Cell Marker	Shows/Hides square for cell identification.
	WBC Attributes	Shows/Hides WBC attributes.
	Entire RBC Image	Shows the entire RBC image.
	Start	
	Stop	

Indicators

	Autostart	Automatic start of slide processing.
	Oil Level Indicators	Indicates an empty oil canister.
		Indicates need for refilling of oil.
		Indicates a full oil canister.
	Output Drawer Indicators	Indicates room left in the output drawer.
		Indicates a full output drawer.
	Hatch Indicators	Indicates all hatches closed.
		Indicates an open hatch or oil immersion arm in wrong position.

	Magazine Indicator	Indicates the number of magazines in the system except those in the output drawer.

Keyboard shortcuts

Ctrl+w	Show/hide Worklist.

Appendix D — Recommended Workflow

Laboratories handle their peripheral blood differential counts in different ways making it hard to suggest one general workflow suitable for all laboratories. See flowcharts of the three workflows below.

Recommended Settings (see 10.7 Adjusting Report/Sign Settings)

1. Single slide differentials

Pre-fill password: Enabled
Sign order when signing the slide: Enabled
Send order to LIS when signed: Enabled

Review the cells in the WBC Galleries.

2. Confirmation of cell counter results - Quickly scanned slides for verification of cell counter results.

Pre-fill password: Enabled
Sign order when signing the slide: Enabled
Send order to LIS when signed: Enabled

Review the analysis type you want to confirm and then click *Confirm Cell Counter Results*.

Confirm Cell Counter Results

When using the *Confirm Cell Counter Result* for any analysis type (WBC, RBC, or PLT) the normal sign slide checks (cells in the Unidentified class, all cells reviewed etc.) are disabled.

Note! *When using Confirm Cell Counter Results the results sent to the LIS are: a WBC confirmation flag, a RBC confirmation flag and/or a PLT confirmation flag*

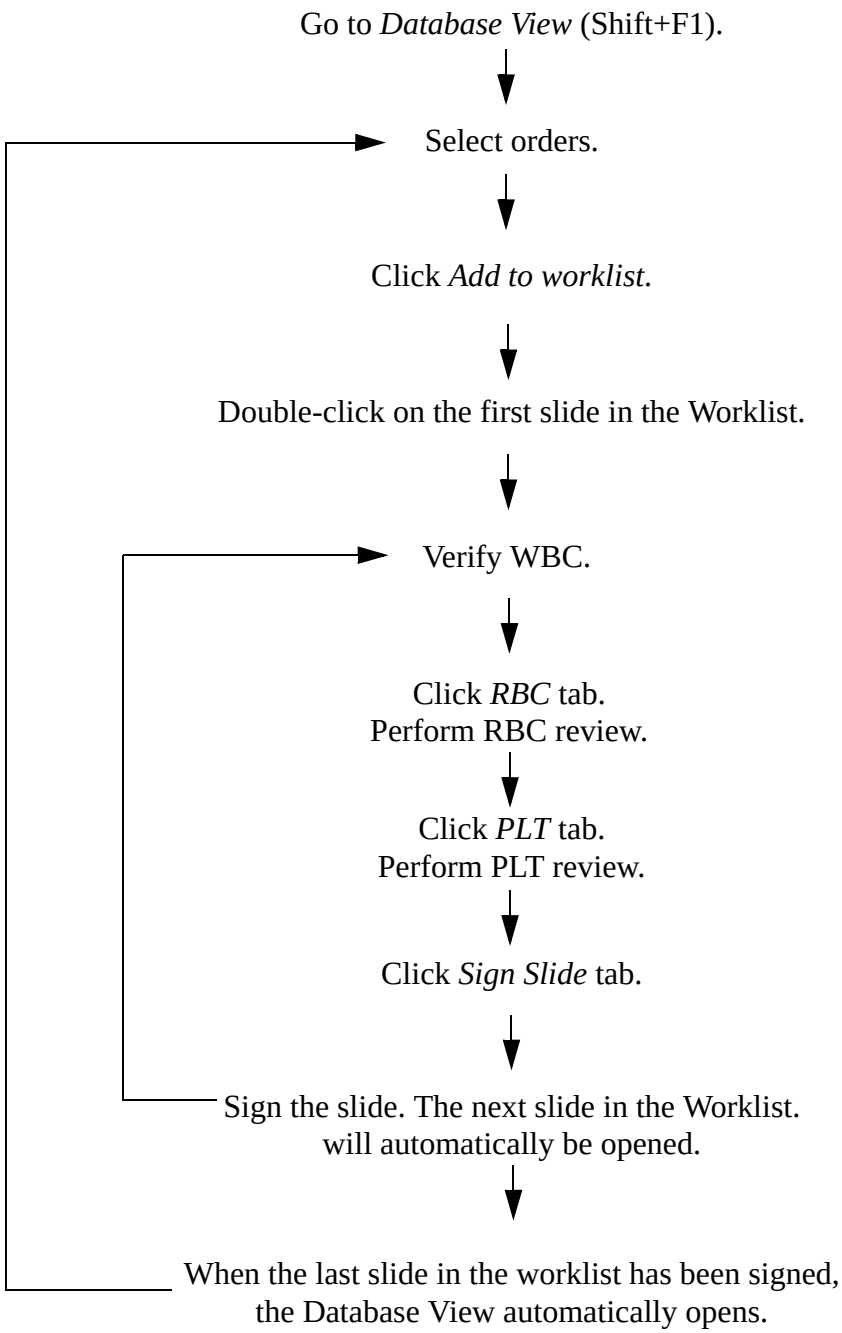
For a slide it is possible to report the WBC result and a RBC confirmation flag and a PLT result or any other combination.

3. Duplicate slides - An order consists of two slides. Two persons sign one slide each.

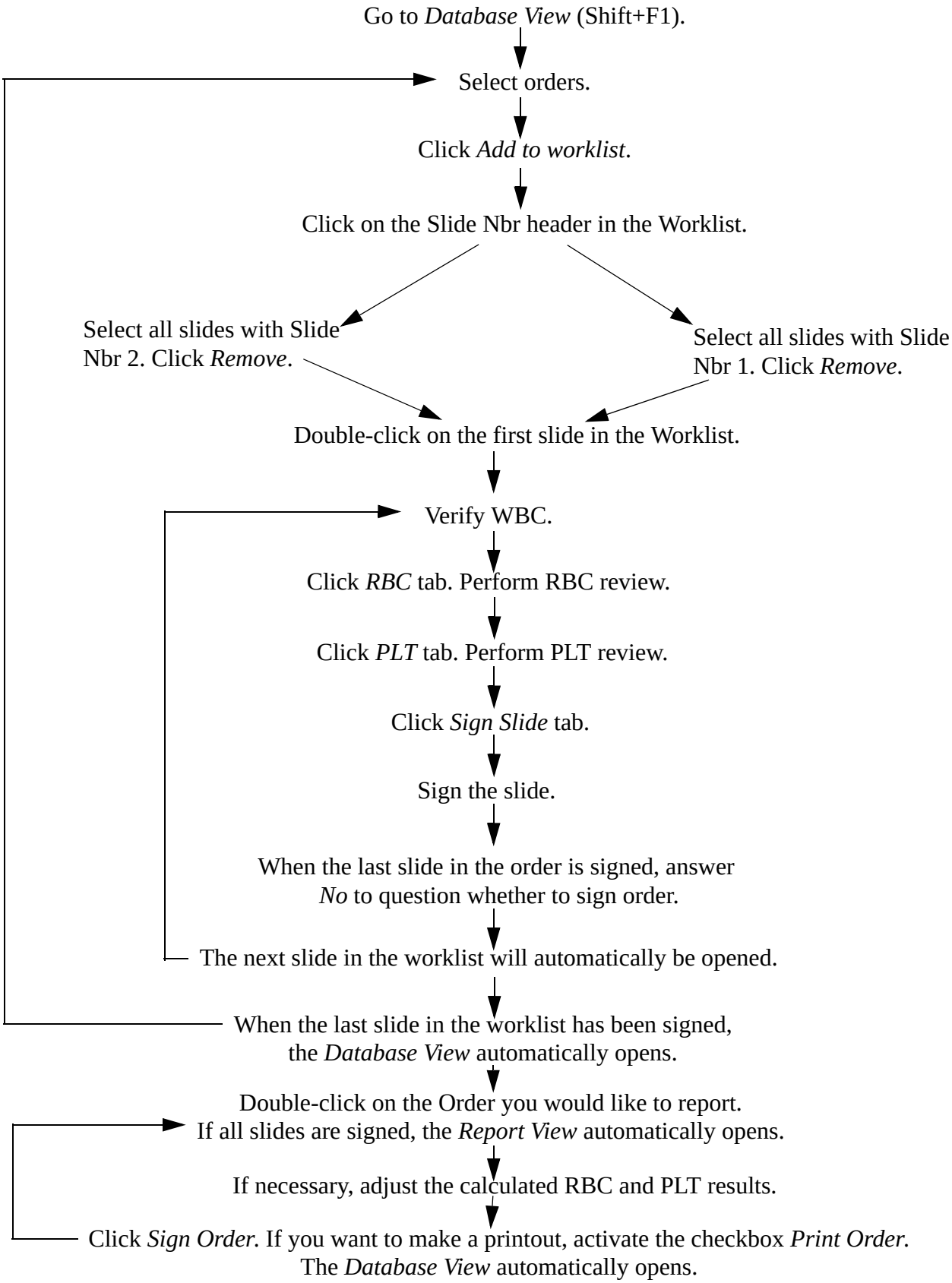
Pre-fill password: Enabled
Sign order when signing the slide: Disabled
Send order to LIS when signed: Enabled

Review the cells in the WBC Galleries.

Workflow Single Slides / Confirm Cell Counter Results


Go to *Database View* (Shift+F1).
Select orders.
Click *Add to worklist*.
Double-click on the first slide in the Worklist.
Verify WBC.
Click *RBC* tab.
Perform RBC review.
Click *PLT* tab.
Perform PLT review.
Click *Sign Slide* tab.
Sign the slide. The next slide in the Worklist.
will automatically be opened.
When the last slide in the worklist has been signed,
the Database View automatically opens.

Workflow Duplicate Slides


Go to *Database View* (Shift+F1).
Select orders.
Click *Add to worklist*.
Click on the Slide Nbr header in the Worklist.
Select all slides with Slide Nbr 2. Click *Remove*.
Select all slides with Slide Nbr 1. Click *Remove*.
Double-click on the first slide in the Worklist.
Verify WBC.
Click *RBC* tab. Perform RBC review.
Click *PLT* tab. Perform PLT review.
Click *Sign Slide* tab.
Sign the slide.
When the last slide in the order is signed, answer *No* to question whether to sign order.
The next slide in the worklist will automatically be opened.
When the last slide in the worklist has been signed, the *Database View* automatically opens.
Double-click on the Order you would like to report.
If all slides are signed, the *Report View* automatically opens.
If necessary, adjust the calculated RBC and PLT results.
Click *Sign Order*. If you want to make a printout, activate the checkbox *Print Order*.
The *Database View* automatically opens.

Appendix E — User Authorization Levels

	Action/Setting	Observer	User	Restricted	Authorized	Administrator
	Start slide processing		X		X	X
	Search in the database on Order ID and Patient ID	X	X	X	X	X
	Search in the database on other criteria	X	X		X	X
	Verify and comment WBC, RBC and PLT		X	X	X	X
	Edit Order data				X	X
	Add/edit pending orders		X	X	X	X
	Sign slides and reports			X	X	X
	Send results to the LIS			X	X	X
	Delete unsigned slides/ orders				X	X
	Delete signed orders					X
	Archive					X
	Export orders				X	X
	Protect order from archiving				X	X
	Send images with e-mail	X	X	X	X	X
	Export log files					X

	Database settings					X
	Users settings					X
	Analysis settings					
	Default values Add processed slide to worklist				X	X
	Enable LIS					X
	Enable autostart					X
	WBC reclassification settings					X
	RBC precharacterization settings					X
	PLT settings					
	Use only manual PLT concentration estimation Defaults for PLT		X	X	X	X
	PLT estimate factor Intervals for average PLTs/HPF					X
	Report/Sign settings					X
	Standard comments settings				X	X
	Reference cells settings				X	X
	E-mail settings					X
	Archiving settings					X

Appendix F — Determining the Platelet Estimate Factor

Follow the procedure below to determine the PLT estimate factor.

1. Perform automated PLT counts with a cell counter on 30 consecutive blood samples.
2. Prepare and stain one smear for each sample.
3. Perform PLT analyses on the system. Let the system calculate the average PLTs/HPF values for each sample.
4. Divide the cell counter PLT value by the system average PLTs/HPF value for each sample to get the conversion factors.
5. Add all 30 conversion factors and divide by 30 to get the PLT estimate factor.
6. Enter the PLT estimate factor in the *PLT* tab in *Settings*.

Appendix G — Slide Preparation Guidelines

Slide Preparation for Peripheral Blood

WARNING

Always use protective gloves when in contact with blood.

Sample

Collect blood from a vein or by skin puncture in an EDTA sample tube (K2EDTA or K3EDTA, 1.5± 0.15 mg/ml in liquid or powder form). Mix the sample carefully with the anticoagulant. Store the tube at room temperature. Prepare the blood films within four hours of blood collection.

Preparing Blood Films

1. Mix the tube (20 complete inversions by hand) before preparation.
2. Use a clean dry microscope glass slide (see Appendix A — System Specification for required slide types). Note that glass slides may lose their wetability on exposure to air, resulting in a poor smear.
3. Use the wedge technique performed manually or by a mechanical spreader. Manual wedge technique: Place a drop of blood near the labeled end of the slide. Narrow a spreader slide with polished edges at a 30- to 45-degree angle to the smear slide. Allow the blood to spread almost over the entire width of the slide. Then rapidly and smoothly push the spreader slide to the opposite end of the slide. There should be a gradual transition in thickness, ending in a squared or straight edge, without any grainy streaks, troughs, ridges, holes or bubbles. The blood film must be at least 30 mm in length, terminating 5- 15 mm from the edge.

(Cont'd)

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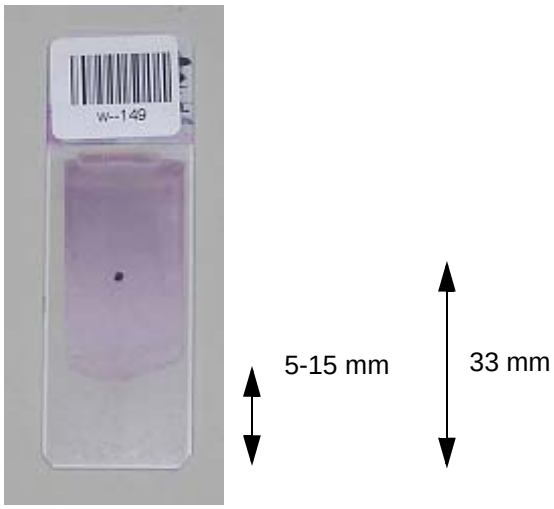
4. Dry the slide rapidly.
5. Stain the slide within one hour.

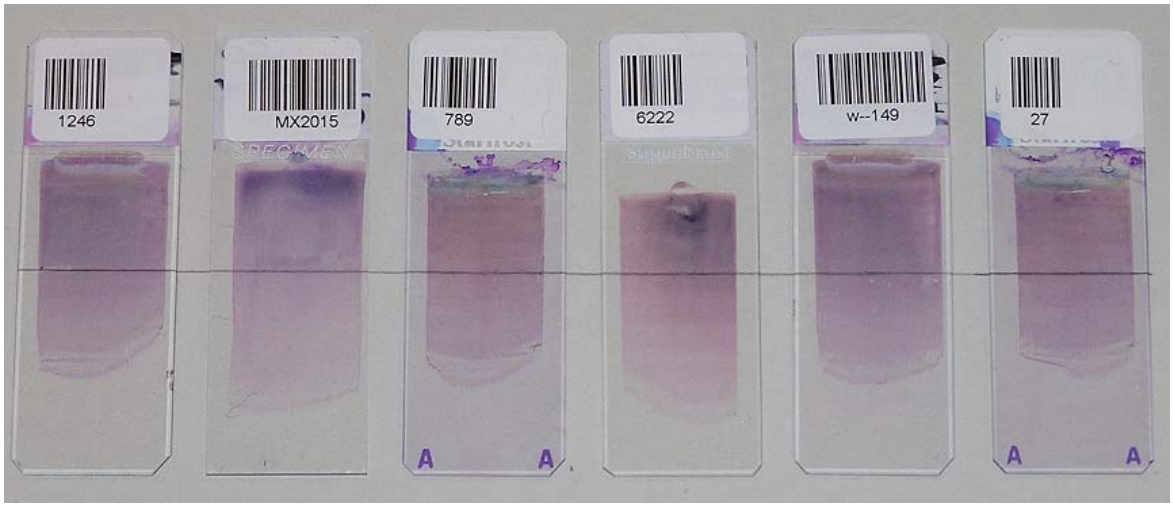


The dot in the image indicates the analysis starting point. The analysis proceeds from the starting point towards the thinner part of the smear.

Example Smears

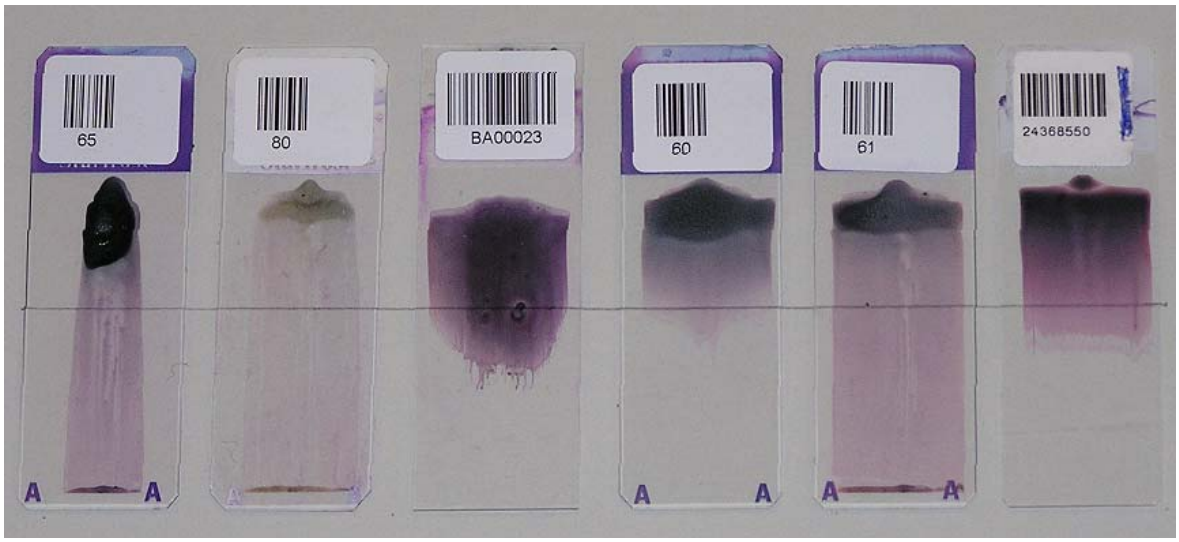
The line in the images indicates the analysis starting point.

Accepted



These slides are all prepared according to the specifications and will be accepted in the DM8/DM96.

Not Accepted



These slides are not prepared according the specifications and will not be accepted in the DM8/DM96

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Recommended Staining Recipes

CellaVision® DM is optimized to analyze samples stained with May Grünwald Giemsa (MGG) stain and Wright stain. Dip the slides in the solutions according to one of the following recipes.

MGG Stain

Note! *Differences in staining results may be cause by alterations in pH, reagents etc. Local adjustments may be needed to achieve best results. Be aware of pH variations in water.*

Alternative 1

	Solution	Reaction time	Change solution
1	May Grünwald stock solution a	5 min	Twice a week
2	May Grünwald working solution b	15 min	Every day
3	Buffer working solution d	Quick rinsing	Every day
4	Giemsa working solution f	30 min	Every day
5	Buffer working solution d	Extensive rinsing	Every day

Alternative 2

	Solution	Reaction time	Change solution
1	May Grünwald stock solution a	5 min	Twice a week
2	Buffer working solution d	Quick rinsing	Every day
3	Giemsa working solution f	10 min	Every day
4	Buffer working solution d	Extensive rinsing	Every day

(Cont'd)

(Cont'd)

a	May Grünwald stain, stock solution:	Merck M1424 Eosin-methylenblue solution, modified for microscopy (contains methanol). Store at +15 ºC to +25 ºC.
b	May Grünwald working solution:	Dilute 1 part of May Grünwald stock solution with 1 part buffer work solution. Stable for 8 hours.
c	Buffer stock solutions 1 and 2:	1) 9.07g KH2PO4 (0.067M) ad 1000ml deionized water Store at +4 ºC to +8 ºC. 2) 9.45 g Na2HPO4 (0.067M) ad 1000ml deionized water Store at +4 ºC to +8 ºC.
d	Buffer working solution, pH 6.8	Combine 127 ml KH2PO4 stock solution with 123 ml Na2HPO4 stock solution ad 5000 ml deionized water. Adjust to pH 6.8. Store at +4 ºC to +8 ºC. Durable for a month at +4 ºC.
e	Giemsa stain, stock solution:	Merck M9204 Azur-eosine-methylenblue solution for microscopy (contains methanol). Store at +15 ºC to +25 ºC. Durable for several months if kept in a dark bottle.
f	Giemsa working solution:	Dilute 1 part Giemsa stock solution with 19 parts buffer work solution. Stable for 8 hours.

(Cont'd)

(Cont'd)

Wright Stain

Note! *Differences in staining results may be cause by alterations in pH, reagents etc. Local adjustments may be needed to achieve best results. Be aware of pH variations in water.*

Alternative 1: Sysmex SMS SP 100 slide stainer

	Solution	Reaction time
1	Wright stain	2 min
2	Wright stain diluted 1:10 with phosphate buffer pH 6.8	7 min
3	Rinse in deionized water	30 sec

Alternative 2: Beckman Coulter GENS slide stainer

	Solution	Reaction time
1	Methanol	30 sec
2	TruColor Wright stain	2 min 30 sec
3	TruColor Wright stain diluted 1:6 with phosphate buffer pH 7.2	6 min 30 sec
4	Rinse in phosphate buffer pH 7.2	1 min 15 sec
5	Rinse in deionized water	45 sec

Wright stain alternative 2 can also be used for manual dip method.

Slide preparation for body fluid

WARNING

Always use protective gloves when in contact with Body Fluids.

Sample

Quantitative assessment of cell counts and preparation of slides should be performed within 2 hours of collection.

Preparing the Sample

Count the WBC and RBC concentration of the fluid. For best results, dilute samples with high cell density.

Buffered saline or standard tissue culture media both with a drop or two of bovine serum albumin (BSA), which promotes cell adhesion to the microscope slide, may be used as a diluent.

The recommendation is to have 5000-12000 cells in total on the slide

Note! *Cells are concentrated approximately 20-fold by cytocentrifugation, however the quantitative yield varies from 30-75%. The speed and time of centrifugation, the amount of sample in the chamber and the filter paper absorbance are factors that can influence both the cell yield and morphology. (ref. Body Fluid Analysis for Cellular Composition, CLSI, H56 A Vol 26, No 26)*

Use a clean dry microscope glass slide (see Appendix A — System Specification for required slide types). Centrifuge the sample according to the manufacturer's recommendation. Dry the slide rapidly.

Note! *Do not use slides with cover slip.*

Stain the slide using the same staining recipe as for peripheral blood samples. (See Recommended Staining Recipes for staining recommendations).

Appendix H — Cell Location

Cell Location for Peripheral Blood

The cell location performance shall be verified at regular intervals and after changes in staining procedure or staining solutions by running the Cell location test. Running the test once or twice a day is a recommended interval at the high-load laboratory. The test establishes how many percent of the nucleated cells (i.e., WBC and NRBC) that are found on a slide.

The Cell Location tool may be accessed in the Tools menu.

Slide Requirements

Use a blood sample with a WBC count in the normal WBC range. To reduce processing time, a WBC count above $7x10^9$/l is recommended. If the system cannot locate at least 100 nucleated cells, the result will be discarded.

The percentage of non-nucleated cells (i.e., all other object that are not identified as being a WBC or NRBC cell, e.g. smudge cells) must not exceed 30% of the total number of objects.

The slides must have a barcode label, starting with the text "QC". All slides with this kind of label are automatically treated as cell location test slides. When the slide has been processed it will only be available in the Cell Location tool. Pre-printed QC labels are available from your local dealer.

Running a Cell Location Test

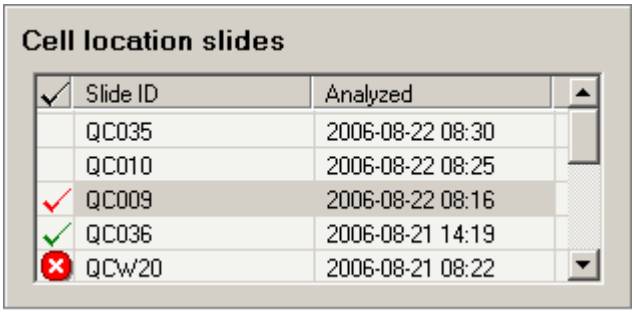
1. Select a slide that meets the requirements and put a QC label on it.
2. Put the slide in a magazine, place it in the DM and process the slide.
3. Go to the Cell Location tool when the slide has finished.
4. Select the new slide at the top of the slide list.
5. Go through all the images belonging to the slide and examine them for missed nucleated cells. Enter the number of missed cells, if any, in the input field for each image.
6. When all images have been examined the result will appear at the end. Check that it is within acceptable limits.

(Cont'd)

(Cont'd)

Examining a Cell Location Slide

Select the slide in question from the list of cell location slides.



Slide status	✓
Empty	Slide has no result (not all images have been examined).
✓	Slide has a result and no missed nucleated cells (all images have been examined).
✓	Slide has a result but contains missed nucleated cells (all images have been examined).
⊗	Slide error, probably due to a failure in slide processing (e.g., not enough nucleated cells were found).

Go through each image in the list of overview images and check if they contain any missed nucleated cells. Green boxes mark the nucleated cells and blue boxes mark other found objects that are not nucleated cells (e.g. artefacts). Missed nucleated cells are those cells not marked with a box in the image. Double-click in the overview image to magnify the area of interest.

Black boxes mark the number of cells that were located but not needed for the test, indicating that the system has located enough cells for the test and is coming to an end.

Note! *On screen, cell images are not always presented in the same order as the system is working. Cells marked with black boxes may occur in the middle of the test, not only towards the end.*

(Cont'd)

(Cont'd)

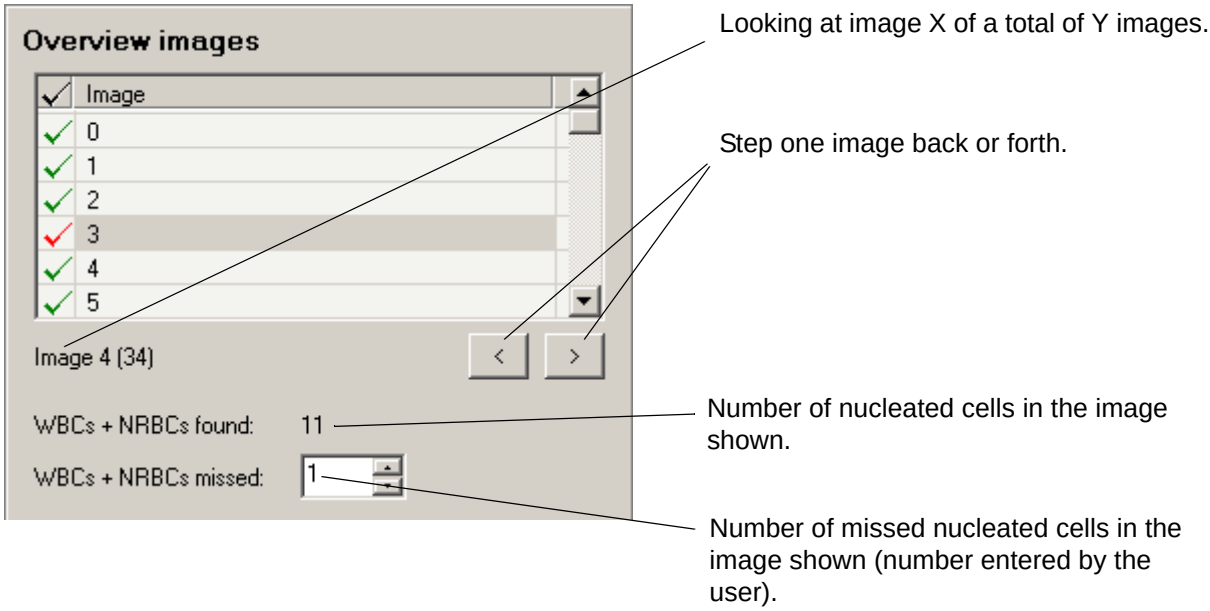


Image status	✓
Empty	Image has not been viewed.
✓	Image has been viewed and has no missed nucleated cells.
✓	Image has been viewed but contains missed nucleated cells.

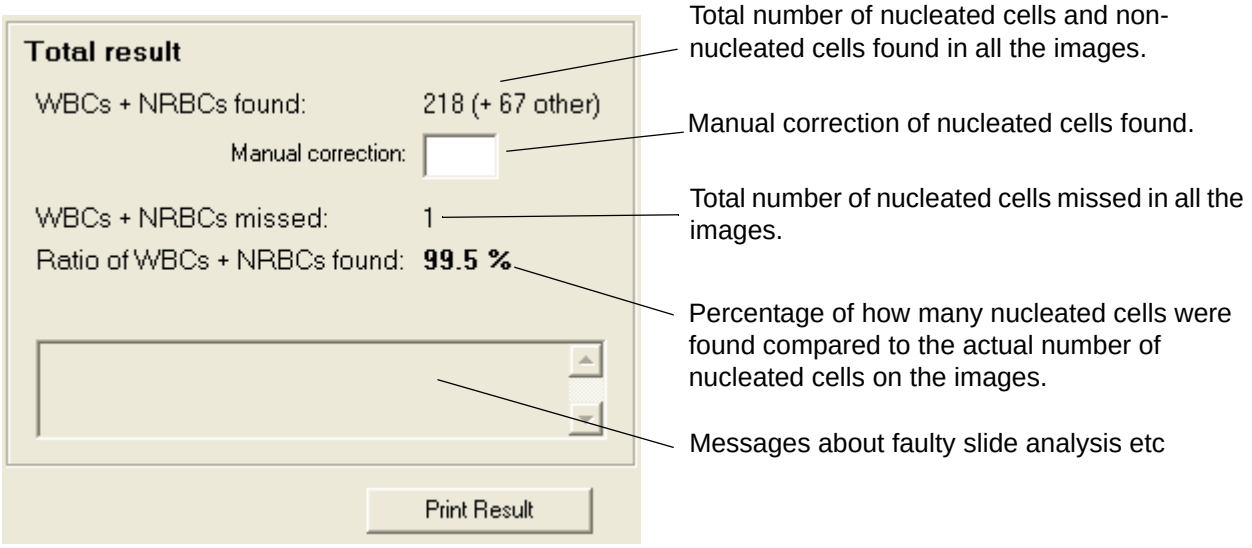
The Result

When a slide has been examined a result is automatically calculated. The percentage indicates how many nucleated cells the system found including the manually added number of missed cells.

It is possible to adjust the total number of found nucleated cells, if it is determined that some found cells are neither WBC nor NRBC cells. For instance, if the system identifies 187 nucleated cells but the user thinks 3 of them do not fall under this category, he/she can enter 184 in the Manual correction field and this number will be used in the calculation.

(Cont'd)

(Cont'd)


Total result
WBCs + NRBCs found:
218 (+ 67 other)
Manual correction:
WBCs + NRBCs missed:
1
Ratio of WBCs + NRBCs found:
99.5 %
Print Result
Total number of nucleated cells and non-nucleated cells found in all the images.
Manual correction of nucleated cells found.
Total number of nucleated cells missed in all the images.
Percentage of how many nucleated cells were found compared to the actual number of nucleated cells on the images.
Messages about faulty slide analysis etc

The result should be compared to the laboratory's own established limits. Performance characteristics when using standardized staining and smear preparation procedures are presented in Appendix A — System Specification.

If any of the requirements regarding the number of nucleated cells or non-nucleated cells are not fulfilled, an error message will be shown in the Total result panel.

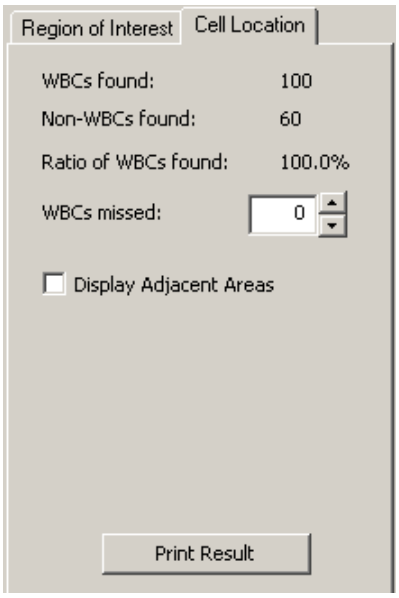
The cell location results can be printed by clicking the *Print Result* button.

Deletion of Cell Location Slides

Slides older than five days are automatically deleted at program startup/logon.

Cell location for Body Fluids

The cell location performance shall be verified at regular intervals and after changes in staining procedure or staining solutions by running the Cell location test. It is also recommended to run cell location test for each new body fluid specimen analysed in the laboratory. For the definition of body fluid specimens see CLSI H56-A Body Fluid Analysis for Cellular Composition; Approved Guideline. Running the test once or twice a day is a recommended interval at the high-load laboratory. The test establishes how many percent of the nucleated cells that are found on a slide.



The Cell Location tool may be accessed by clicking on the cell location tab in the body fluid overview view. Cell location information is available for all BF slides.

Slide Requirements

Use a body fluid sample with a total number of WBCs less than 12000.

Running a Cell Location Test

1. Select a slide that meets the requirements and process it like a regular BF slide.
2. Open the slide and go to the Overview and select the Cell Location tab.
3. Navigate through the entire analysis area and look for missed nucleated cells. Enter the number of missed cells, if any, in the input field.
4. When the entire area has been viewed, check that the result it is within acceptable limits.

Note! *It is recommended that you order 10x+50x overview images for cell location slides.*

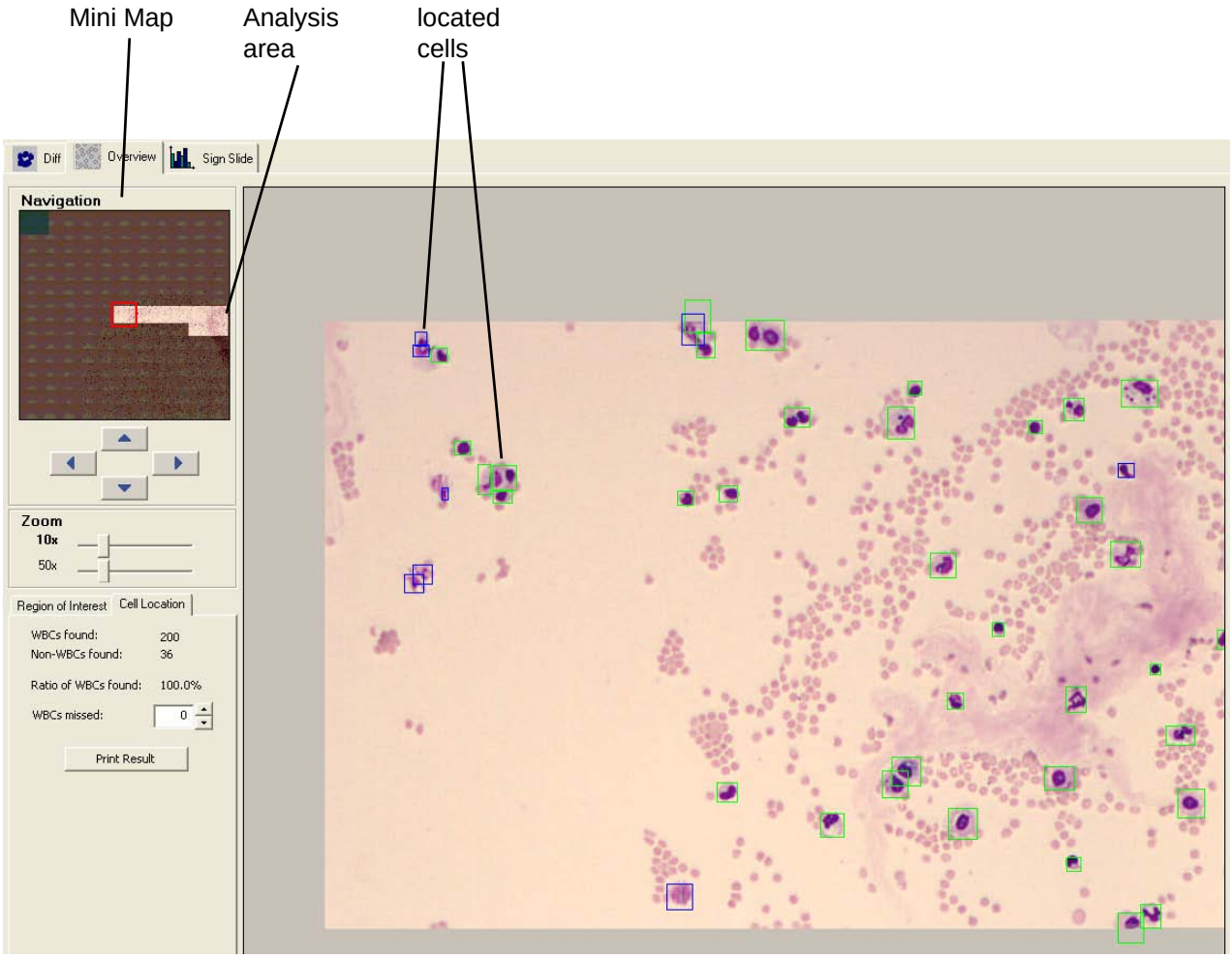
Note! *QC labels are not required for running cell location test on body fluid slides.*

(Cont'd)

(Cont'd)

Examining a Cell Location Slide

Open the slide in question from the database view.



The analysis area used for collecting cells is represented by the bright part of the mini map.

Navigate through the analysis area and check if it contains any missed nucleated cells. Green boxes mark the nucleated cells and blue boxes mark other found objects that are not nucleated cells (e.g. artefacts). Missed nucleated cells are those cells not marked with a box in the image.

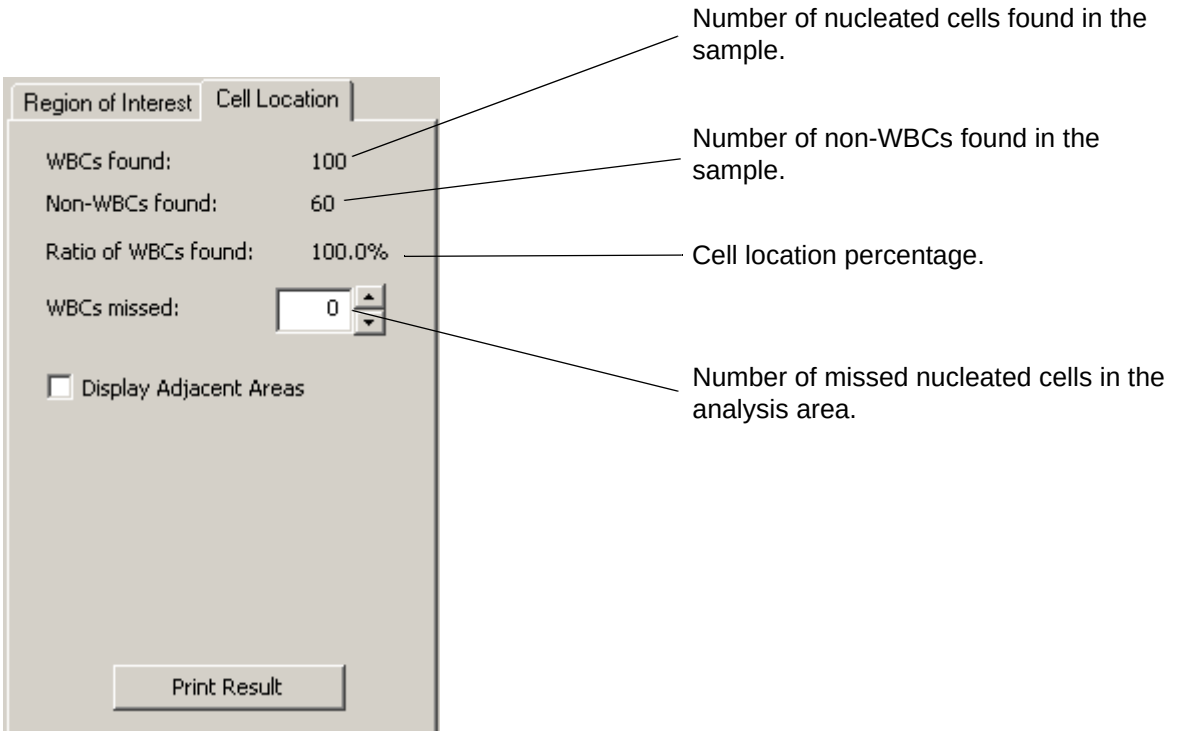
(Cont'd)

(Cont'd)

Black boxes mark the cells that were located but not needed for the test, indicating that the system has located enough cells for the test and is coming to an end.

Note! *On screen, cell images are not always presented in the same order as the system is working. Cells marked with black boxes may occur in the middle of the test, not only towards the end.*

Note! *The last collected cell will be marked with both a black and a green or blue box.*



The Result

The result is automatically calculated. The percentage indicates how many nucleated cells the system found including the manually added number of missed cells.

The result should be compared to the laboratory's own established limits. Performance characteristics when using standardized staining and smear preparation procedures are presented in Appendix A — System Specification.

The cell location results can be printed by clicking the *Print Result* button.

Appendix I — Glossary

	Description
Analysis	Starts with the loading of slides and ends with the finished report.
Confirmation	The operator approves the preclassification.
Duplicate slide differential	Two different persons sign one slide each in the order. The average result is presented.
Grid square	Sub-images of a PLT overview.
In-vitro	Outside the living body; in an artificial environment.
LIS	Laboratory Information System
Magazine	A container transporting up to 12 slides in the system.
Magazine ID	The barcode no. on the magazine label for magazine identification.
MGG	May Grünwald Giemsa; a Romanowsky stain for blood smears.
Mini map	Overview image of analysis area.
Multi-slide order	An order including more than one slide from one sample.
Non-WBCs	Cells and objects identified as not being WBCs.
Not classed	Cells and objects the operator cannot identify and wants to exclude from the differential count.
Operator	The person who works with the system.
Order	The name of the ordered analyses on the slides from the same sample.
Order ID	Order identifier. There can be several slides with the same Order ID but different slide numbers.
Other	Cells that the operator identifies as WBCs, but of a type other than those listed. Will be included in the differential count.
Patient ID	Unique number identifying the patient.
Pending order	An order manually added to the database, waiting to be processed.
PID	Positive Identifier. The barcode on the slide.
PLT	Platelet, thrombocyte
PLT estimate	Estimation of the PLT concentration.
PLT estimate factor	A predetermined factor to calculate the PLT estimate.
Precharacterization	The system suggests RBC morphology characteristics.
Preclassification	The system suggests WBC classification.
Processing slides	The sequence of events from when the slide holder is put on the conveyer to when they are ejected to the output drawer.
Quick scans	Quickly scanned slides for cell counter verification. The results are not sent to the LIS.
RBC	Red blood cell, erythrocyte
Reclassification	The operator changes the preclassification.

Reference cells	Cells with typical characteristics available in the 2nd and 3rd galleries.
Region of interest	Part of the BF or Scan overview image tagged by the operator.
Romanowsky stain	An eosin-methylenblue solution for staining of blood smears. Wright and MGG are examples of different Romanowsky stains.
Signing	Finally confirming analysis results before locking and reporting them.
Slide ID	The barcode number on the slide (PID). Same as Order ID.
Slide number	A number that uniquely identifies slides within the same order.
Slide position	The position of a slide in the magazine.
Unidentified	Cells and objects which the system cannot preclassify.
Verification	The operator's review of WBC, RBC and PLT, e.g. reclassification and confirmation of WBCs.
WBC	White blood cell, leukocyte
Wright	A Romanowsky stain for blood smears.

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